STATEMENTS OF MARGARET A. HAMBURG, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, AND LAUREN SMITH, INTERIM COMMISSIONER, MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF MARGARET A. HAMBURG

Ms. Hamburg. Mr. Chairman and members of the subcommittee, I am Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration. And I am joined by Howard Sklamberg, Deputy Associate Commissioner for Regulatory Affairs.

Thank you for this opportunity to testify about the tragic fungal meningitis outbreak associated with an injectable steroid product distributed by NECC and for our safety concerns related to compounding and the legislation that is needed to prevent such incidents from happening again.

I want to begin by offering my deepest sympathies to the patients affected by this outbreak and their families. This event has had devastating effects on patients across the country, such as Eddie Lovelace, Judge Lovelace, many of whom were likely unaware that they were being treated with a compounded product not reviewed or approved by the FDA.

Our foremost goal is the protection of the health of the public. Since the onset of this outbreak, we have targeted FDA resources, from experts in our headquarters to inspectors and scientists in district offices and labs across the country, to do everything we can to stem the toll of this terrible event. Together with CDC and the States, we have sought to identify potentially contaminated products and ensure that they are removed from the market and do not reach patients. We have collected and analyzed hundreds of samples from the relevant firms, as well as from medical facilities and State and local agencies, to isolate the cause and determine the extent of the contamination.

We are working daily to ensure timely, clear, and accurate information is disseminated about the findings of our investigation, what products are affected, and what providers should do with any products still on their shelves. And we are working to alleviate existing drug shortages exacerbated by product recalls.

We have also been reviewing actions taken in the past with regard to NECC. From our review thus far, we have no reason to believe that any of the specific actions in question, a more timely issuance of the 2006 warning letter, or inspectional follow-up, would have prevented this recent tragedy.

What we do know is that stronger, clearer authority would enable more effective regulation of the drug-compounding industry, especially when it has been evolving so significantly. As it is, our authority over compounding is limited, unclear, and contested. And in the face of differing views in Congress and the courts about FDA's authority and continuing challenges by industry, the agency has struggled with how to chart an effective course to protect the public health.

We recognize that traditional compounding provides an important service for patients who, for example, can't swallow a pill or are allergic to an ingredient in a drug product. But the industry has evolved well beyond the neighborhood

pharmacist. In particular, the movement by many hospitals to outsource pharmacy compounding has created a market for compounding operations that produce drugs that reach far larger numbers of patients. When these facilities operate well, they may serve an important function in terms of safety and efficiency. However, when they fail to follow safety and quality standards, many patients may be harmed.

Our best information is that there are thousands of other compounders out there producing what should be sterile products made to exacting standards, and, thus, many other firms with the potential to generate a tragedy like this.

The current oversight framework, in attempting to draw a bright line between compounders and manufacturers, fails to address the complex issues raised by a changing industry. Additionally, gaps and ambiguities in the law have hampered our ability to act to protect patients and to prevent rather than just react to safety concerns.

I am committed to working with Congress and other stakeholders to design a system of rational, risk-based regulation that takes into account both the Federal and the State roles. As I outlined in my testimony, we have developed a proposed framework that would tier the degree of oversight to the risk posed by the type of product and practices. Traditional compounding would remain the purview of the States. The higher risk posed by nontraditional compounding would be addressed by Federal standards, including standards for quality control.

And under this framework, certain products carrying the highest risk could not be compounded. They could only be produced by entities willing to meet the standards currently required of drug manufacturers.

We would like to explore with you authorities that would be important to support this new regulatory paradigm, including clear authority to access records, mandatory reporting of adverse events, additional registration requirements to facilitate appropriate oversight and coordination with State regulators, clear label statements to allow prescribers and consumers the opportunity to make informed judgments, and adequate funding to support the inspections and other oversight activities outlined in this framework.

And because a key piece of any plan involving oversight of pharmacy compounders will continue to be performed at the State level, we must work closely with our State partners as we develop the framework for new authorities. Consequently, FDA will be inviting representatives from all 50 States to participate in a full-day meeting on December 19th to facilitate these important discussions.

We have a collective opportunity and responsibility to help prevent future tragedies. If we fail to act, this type of incident will happen again. It is a matter of when, not if. If we fail to act now, it will only be a matter of time until we are all back in this room, sadly, asking why more people have died and what could have been done to prevent it.

I am happy to answer any questions you may have.

Mr. Stearns. I thank you.

[The prepared statement of Ms. Hamburg follows:]

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Mr. Stearns. Dr. Smith, for your summary of your opening statement?

STATEMENT OF LAUREN SMITH

Ms. Smith. Thank you, Chairman Stearns, Ranking Member DeGette, and members of the committee. Thank you very much for having me here today. My name is Dr. Lauren Smith, and I am the interim commissioner of the Massachusetts Department of Public Health.

I have to also begin by saying that my thoughts are with the victims and families affected by this tragic outbreak and with Mrs. Lovelace, whose moving testimony only strengthens my resolve to ensure that no other family has to suffer what she aptly described as the heartbreak that hers has. As a mother, a pediatrician, and a public health leader, I have devoted my life and career to protecting the health of others. These events evoke in me the same sense of outrage as they do for you and the rest of the public. For many of you, I know this hits very close to home.

For the past 2 months, our department, along with the FDA, has conducted a joint investigation of New England Compounding Center, the source of this devastating fungal meningitis outbreak that has sickened hundreds and killed 31 people across the country. We have also investigated and shut down NECC's sister company.

NECC knowingly disregarded sterility tests, prepared medicine in unsanitary conditions, and violated their pharmacy license, endangering thousands of lives as a result. NECC bears the responsibility for the harm that they have caused with these actions.

I was given the responsibility, as interim commissioner, less than 3 weeks ago to lead my department through this crisis, and, like you, I have been trying to put together the pieces of the puzzle.

First licensed by Massachusetts in 1998, NECC and its owner, Barry Cadden, have since been the subject of numerous complaints, resulting in a series of investigations by the State and the FDA. These investigations led to the Board of Pharmacy's proposed reprimand and probation in 2004. This proposal was inexplicably weakened in 2006, allowing NECC to continue to operate without disciplinary actions, pending an independent evaluation of its progress under a consent agreement. The Board of Pharmacy's failure to take decisive disciplinary action in 2006 on these complaints has contributed to these tragic events.

In April of 2006, the Board of Pharmacy's staff learned that the principal of PSI, the evaluator for NECC, had been convicted of Federal crimes that resulted in 18 people being blinded. However, the staff did not share this information with board members before they accepted the report from PSI validating NECC's compliance with the consent agreement. These same staff members failed to act on a July 2012 report from the

Colorado Board of Pharmacy that NECC had violated both Colorado and Massachusetts pharmacy regulations. These staff have been removed from their jobs.

Poor judgment, missed opportunities, and a lack of appropriate action allowed NECC to continue on this troubling path. We acknowledge that these lapses--some of which were preventable, but all are unacceptable.

From the early days of this outbreak, our department has acted swiftly and decisively. We secured a surrender of NECC's license, shut down its operations, and forced a total recall of all NECC products. We moved to permanently revoke NECC's license as well as the licenses of the three principal pharmacists who oversaw their operations. We also secured the suspension of operations of Ameridose and Alaunus, two other drug manufacturers owned by Barry Cadden, which, as you know, have been found to have similar substandard practices.

While taking these strong and necessary actions, we have reexamined our own State regulations regarding compounding pharmacies. Although our regulations are comparable to those in most States, they need to be strengthened to address the realities of this evolving industry.

On November 1st, Massachusetts enacted a series of emergency regulations to bring greater scrutiny to this industry and require sterile compounding pharmacies to report both volume and distribution information to us. Licensed pharmacies will also have to report when they are the subject of any State or Federal investigations. We have also begun unannounced inspections of all sterile compounding pharmacies in Massachusetts. Teams are conducting these inspections even as we speak.

To further strengthen our oversight over sterile compounding pharmacies, we must explore changes to the law. We have created a special commission to review best practices in other States and to identify stronger mechanisms for oversight for these pharmacies in Massachusetts.

As we work to raise standards in our State, we urge Congress to act to strengthen Federal oversight. Congressman Markey's leadership on this issue is laudable and would address some of the regulatory black holes that exist between State and Federal oversight.

As a pediatrician who has cared for acutely ill children and their families for almost 20 years, I must say that I understand the trust that patients place in our healthcare system. We must use these tragic events as an impetus to work together--public health leaders, public health officials, and legislators--to institute reforms to restore this trust and to ensure that something like this does not ever happen again.

We will keep the victims and their families always in our thoughts--they are not numbers, they are not statistics, but real people with real lives--as we work to identify responsibility and to implement policies and practices that can be effective and lasting.

Thank you. I appreciate the committee's interest in this matter, and I am grateful to you for acting so swiftly to have us come here to discuss it.

[The prepared statement of Ms. Smith follows:]

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Mr. Stearns. Thank you, Dr. Smith.

Commissioner Hamburg, the title of this hearing is ``The Fungal Meningitis Outbreak: Could It Have Been Prevented?''

Now, your testimony is 16 pages long. There is one sentence on FDA oversight on the New England Compounding Center prior to the outbreak. Now, this was--this is an investigative hearing. This was a complete and utter failure on the part of your agency and--Dr. Smith in her testimony admitted--and the State Board of Pharmacy. The committee's memorandum that we did, we had 25 pages laying this out. Yet you devoted just 1 sentence of your 16 pages in your opening statement that even talked about this oversight.

Over the years, the FDA repeatedly--repeatedly documented numerous problems at the NECC. Many of these problems are similar, if not identical, to the same problems which caused this outbreak. The agency ultimately issued a warning letter in 2006, 6 years ago, stating that if the company did not alter its practices, FDA would seize its product or issue an injunction and effectively shut down NECC.

Now, we heard Dr. Smith; you heard her testimony this morning. She talked about the mistakes they made and what they are going to do to correct it. You are here with your opening statement, you are practicing plausible deniability is what you are practicing.

When FDA issued the 2006 warning letter, did FDA have the authority to do what it said--namely, seize the drugs and shut down the committee--the company? Yes or no?

Ms. Hamburg. I think it is important--the fact is----

Mr. Stearns. No, the question is, did you have the authority----

Ms. Hamburg [continuing]. The one letter did not involve sterility failures, and it was not in relation to the kinds of problems that we are addressing now.

Mr. Stearns. So you are saying your letter was an empty threat?

Ms. Hamburg. You know, I think one of the great challenges----

Mr. Stearns. No, the real question is, did you think you had the authority----

Mr. Waxman. It wasn't her letter.

Ms. DeGette. It wasn't her letter.

Mr. Stearns. Well, not your letter, personally, but----

Ms. Hamburg. I think it is important to understand that I was not at----

Mr. Stearns. No, I understand that and I appreciate that.

Ms. Hamburg [continuing]. The FDA at the time and that----

Mr. Stearns. And I am just staying that the frustration we have is----

Ms. Hamburg [continuing]. The warning letter and the inspection it was based on had to do with a different set of complaints than sterility failures----

Mr. Stearns. Let me rephrase the question. Do you think the FDA had the authority to shut down NECC? Yes or no?

Ms. Hamburg. I think that is a very, very complex question and that the legal framework----
Mr. Stearns. So you can't answer that question now?
Ms. Hamburg [continuing]. For FDA activities is----
Mr. Stearns. OK, let me ask another question.
Ms. Hamburg [continuing]. Very, very unclear----
Mr. Stearns. If you are not going to answer this question----
Ms. Hamburg [continuing]. Contested, and limited.
Mr. Stearns. [continuing]. Let me ask you----
Mr. Waxman. May she answer the question?
Mr. Stearns. Well, she is not answering the question, Mr. Waxman.
Mr. Waxman. She is trying.
Mr. Stearns. Well, I had asked her ``yes or no,'' and she won't answer the question.
Ms. DeGette. She can't.
Mr. Stearns. This is my--my questions can be asked. You can ask your question.
Ms. Hamburg. You know, I think that the answer to your question is that, even on much smaller regulatory actions, the FDA authority to act was contested. Even going into NECC to do that inspection in 2004----
Mr. Stearns. OK. Let me interrupt you----
Ms. Hamburg [continuing]. We did not get access to the records immediately.
Mr. Stearns. I am asking the questions, and I only have so much time.
You issued the letter in 2006. You said you were going to shut it down if they didn't improve on their quality assurance. Was that an empty threat?
Ms. Hamburg. The----
Mr. Stearns. Did the FDA think they had the jurisdiction, they had the responsibility to shut it down?
Ms. Hamburg. The warning letter concerned, first and foremost, an issue that had to do with making copies of a commercially available drug.
Mr. Stearns. We have a different interpretation----
Ms. Hamburg. It was a different issue.
Mr. Stearns [continuing]. Of my question. Let me interrupt you and ask you another question.
When the FDA inspected the NECC in 2002--that is 10 years ago--there was evidence that people had been infected by contaminated NECC products. Some of those people were experiencing meningitis-like symptoms.
What proof did the company provide then that it had corrected these problems?
Ms. Hamburg. Well, as I think you understand from the documents we provided and the information that has been discussed, it was--we went in and we found problems, and we worked closely with the Massachusetts Board of Pharmacy to address them. But it was determined that the primary responsibility for overseeing NECC was Massachusetts because they were operating as a compound pharmacy----
Mr. Stearns. So you were deferring to the State of Massachusetts?
Ms. Hamburg. Well, we worked with the State. We----

Mr. Stearns. OK.
Ms. Hamburg [continuing]. Tried to provide help and assistance.
Mr. Stearns. All right.
Ms. Hamburg. But the responsibility for assuring----
Mr. Stearns. So it is not your job; it is the State of Massachusetts'. OK.
Ms. Hamburg [continuing]. Compliance with sterility issues was, in fact----
Mr. Stearns. Let me ask this last question.
Ms. Hamburg [continuing]. Not our direct responsibility.
Mr. Stearns. Before the current outbreak, the last time FDA inspected the NECC was in January of 2005, which led to the warning letter. The warning letter stated that FDA may conduct follow-up inspections to ensure that the NECC was in compliance.
There was not a single follow-up inspection that occurred after 2005; is that correct? Yes or no?
Ms. Hamburg. That----
Mr. Stearns. Do you want me to repeat the question? There was not a single follow-up inspection that occurred after 2005.
Ms. Hamburg. We did not do----
Mr. Stearns. OK.
Ms. Hamburg. Again, I have to----
Mr. Stearns. OK. That is a ``yes.''
Ms. Hamburg [continuing]. Make clear that I was not present----
Mr. Stearns. All right, let me finish.
Ms. Hamburg [continuing]. At the FDA at the time.
Mr. Stearns. After noting----
Ms. Hamburg. And it is my understanding----
Mr. Stearns. OK.
Ms. Hamburg [continuing]. And I cannot speak----
Mr. Stearns. OK.
Ms. Hamburg [continuing]. To all of the issues that were involved there, but----
Mr. Stearns. You are taking my time. Let me finish.
After noting violations upon violation--violations upon violation in 2002 through 2005, why did the FDA feel confident that the NECC would correct its violations and obey the law? I mean, you had from 2002 to 2005 all these violations. What made you think that they would correct them? And not you, personally; I understand you weren't there.
Ms. Hamburg. With respect to the first violations concerning the sterility issues, those were very serious concerns. We acted aggressively, in partnership with the State of Massachusetts.
But the day-to-day responsibility for overseeing the practice and remediating the sterility failures were taken on by the State of Massachusetts, who had the primary day-to-day oversight of this compounding pharmacy. A consent decree was reached in 2006, and we had understood, as had the Massachusetts Board of Pharmacy, that they were appropriately addressing those sterility concerns.
We had gone in in relation to a different complaint from a company about the copying of an FDA drug. And in that instance--we went in in relation to the manufacture of a

specific product, trypan blue--it was not an issue of sterility failure or the conditions in the facility, but it was a practice that we felt they should not be pursuing, and that was what we were trying to address.

Mr. Stearns. My time has expired, and I recognize the ranking member from Colorado, Ms. DeGette.

Ms. DeGette. Thank you very much, Mr. Chairman.

Dr. Hamburg, I want to try to clarify what is going on here, so I would appreciate short answers also.

Now, most of the FDA inspections into this manufacturer, NECC, were about 10 years ago, correct? And that was under the FDA under the Bush administration, correct?

Ms. Hamburg. That is correct.

Ms. DeGette. OK. Now, in 1997--I was actually here then--the FDA Modernization Act excluded the small--well, it excluded drug compounders, for the most part; is that correct?

Ms. Hamburg. That is correct. If a pharmacy was operating in accordance with certain conditions, then they were excluded.

Ms. DeGette. So the FDA didn't have authority over those types of compounders, correct?

Ms. Hamburg. That is correct.

Ms. DeGette. So after the 1997 act was passed, when the FDA received complaints about drug compounding, it had to go over the hurdle of determining whether those conditions had been met or not before the FDA was determined to even have authority; is that correct?

Ms. Hamburg. Correct.

Ms. DeGette. So what happened here is that the FDA was contacted in 2002 about some problems. They went into NECC, they found some problems, and there was a whole series of investigative efforts after that, correct?

Ms. Hamburg. Yes.

Ms. DeGette. And one of the issues in this case and in other cases was whether the FDA even had authority to be investigating complaints, whether or not this particular manufacturer fell under the appropriate criteria, right?

Ms. Hamburg. With respect to the public health threat that was identified in 2002, we went in and aggressively investigated and worked with the State of Massachusetts to get those contaminated products recalled to prevent ongoing damage to patients. Then, because this was a compounding pharmacy, with the primary responsibility for oversight resting with the Massachusetts State Board of Pharmacy, they were responsible for the efforts----

Ms. DeGette. ``They''? Who is ``they''?

Ms. Hamburg. The Massachusetts State Board of Pharmacy.

Ms. DeGette. Massachusetts was primarily responsible because it was a compounding pharmacy, right?

Ms. Hamburg. Because it was a compounding pharmacy.

Ms. DeGette. OK. So, in other cases, not particularly NECC but in other cases, when the FDA tried to assert jurisdiction over compounding pharmacies in similar situations, they were actually sued in court, the FDA was sued in court by these companies, saying the FDA didn't have jurisdiction over these pharmacies, correct?

Ms. Hamburg. That is correct.

Ms. DeGette. And, in fact, there is a court case that

covers part of the whole country that says the FDA doesn't have jurisdiction; is that right?

Ms. Hamburg. The challenge we have today is that there is a patchwork of legal authorities that really oversee the regulatory actions that we can take. We have a split circuit court decision. There is a map that we have that shows that, you know, unfortunately, we have unclear, fragmented legal regulatory frameworks that make it very hard to understand how best to exercise enforcement.

Ms. DeGette. Well, and so if you have an emergency like this, if you have an emergency like this, sometimes what you are afraid of is--you are going to act aggressively, but you are afraid that you are going to be hauled into court. And that is why oftentimes you go to the State regulatory agency; is that correct?

Ms. Hamburg. Absolutely. The fact that we have unclear, limited, and contested authorities and ambiguities in the law and a crazy quilt of legal authority has required us to be very reactive, responding to those serious public health threats, and selective. And, of course, every effort is resource-intensive, as you say, and often will end up in litigation.

Ms. DeGette. OK, so let me ask you this: If Congress clarified what we meant in the 1997 act with these large compounding pharmacies, that we, yes, indeed, intend to give the FDA jurisdiction, that will help you be able to protect these patients better by either doing inspections to prevent these problems in the first place or by requiring quick recalls; is that correct?

Ms. Hamburg. Absolutely.

Ms. DeGette. Thank you.

Ms. Hamburg. We clearly need additional authority.

Ms. DeGette. I just want to ask a really quick question of Dr. Smith.

I really appreciate the efforts that you are making since you took over. But, again, most of these things that happened--in fact, all of these things that happened--happened before your tenure, Dr. Smith.

And I guess I would like to know--and in reading all the documents and all of the history of this, it is obvious to me that the ball was dropped, and dropped in a big way, by the Massachusetts regulators. And so my question is, what is Massachusetts doing now to make sure this never happens again?

Ms. Smith. Well, I agree with you that there were certainly missed opportunities and lapses of judgment that demonstrate significant irresponsibility. And we have taken action with the staff that demonstrated that.

In terms of what we are doing now, I think the highlight would be the enactment of the emergency regulations, importantly, which would require sterile compounding pharmacies to produce information regarding volume and distribution--the volume issue being so important because if you are making numerous batches, thousands of vials of material, then effectively you are acting more like a manufacturer than the more traditional compounder.

We also require pharmacies to provide information on any State or Federal investigations that concern them. That would allow us to have known that your State's board of pharmacy had,

in fact, issued a cease-and-desist to NECC in April of 2011 for this same issue of providing bulk prescriptions that were not patient-specific.

And, lastly, we have done the--convening a special commission to really understand what are the best practices in strengthening the oversight of this evolving industry.

We clearly are committed to making sure that this doesn't happen again, and we want to do everything in our power to do that.

Ms. DeGette. Thank you.

Thank you very much, Mr. Chairman. I appreciate your indulgence.

Mr. Stearns. The chairman of the full committee, Mr. Upton, the gentleman from Michigan.

Mr. Upton. Thank you, Mr. Chairman.

I just want to remind all of us here that this committee has a very long tradition, even before John Dingell, of working with strong members to identify problems in this country, to expose that, and then coming back with legislation to fix it so it doesn't happen again.

And one of those, as we all review this case and see what was there--the recent inspection, the visible black particulate, the tacky mats, the leaking boiler, the bird flying around--I mean, it is just, what gives? I mean, if this was found just recently--and it is our understanding that there were similar types of contamination in earlier years--what is the problem without--what is the problem by not shutting down something like this until it is corrected?

And if you don't have the authority, then we need to make sure that it is there. And it seems pretty reasonable to me that, in fact, you did have the authority to not only have unannounced inspections but to come in and correct it so that it didn't get to this stage.

Certainly, with the deaths of people across the country and the questions that are raised today, as part of the tradition of this committee, we have to have the right information to find out if something is off track or whatever.

And I guess one of the concerns that I have is that, in a bipartisan letter that was sent nearly a month ago, we asked the FDA for documents, for internal communications, to find out what discussions were going on, what was the feedback from the company. And it is my understanding that to date we have some emails that have come back but not anywhere close to what we ought to have as we really try to move an investigation forward and try to get to the very bottom of this and make sure that it never can happen again.

And I would ask Commissioner Hamburg if we can have a commitment from you, as it relates back to the letter that we sent on October 17th, that we get the full cooperation from your staff so that we can come back and ask questions and really try to get to the bottom of this to identify where are the problems. Because, clearly, they were there, right?

Ms. Hamburg. We will work very hard with you. We appreciate the work this committee is undertaking. We have tried to get you documents in a timely way. We have, you know, so far been able to get you----

Mr. Upton. Not very many.

Ms. Hamburg [continuing]. You know, the 2,000 pages of documents. But, unfortunately, we are also pursuing the active public health investigation response, and many of the same people that are involved, have the right expertise and knowledge of the issues, are working on that at the same time that we are trying to get you that information.

And of course, as Congresswoman DeGette pointed out, this concerns activities, some of it going back many years to a different administration and different employees at the FDA. So we are going through, trying to get all those documents, and we will be continuing to provide you with the information you have requested.

Mr. Upton. Well, I just want to say, I had a long discussion last month during the break with my colleague from Michigan, Mr. Dingell. Very frustrated about what was going on. Wanting to get to the bottom of this, wanting to make--you know, as we all think about the FDA's proper role, I mean, this would be it. I mean, as we all identify facilities in our own districts--I know that when I go visit, it is clean as a whistle. It really is. The people are proud to have the jobs that they have. It is as sterile as you can imagine.

And I can't, you know, for the life of me, as we read about this information from eyewitness accounts and inspections that were there before, and to have it go on and on and on without a follow-up, without--I mean, that is not--that is not what anyone is expecting the FDA to do. When you find this stuff, it needs to stop.

And, as Americans, we demand that for manufacturing here. We also expect it to happen overseas. And your inspections in China and other places, that the products that are being produced are safe, not only for Americans but all humans. And when we--you know, we get terribly frustrated.

I know you tried to call me yesterday afternoon. It was my first day back. And we are going to continue to communicate, I can assure you.

But we want to get to the bottom of this. We want to find out what really did break down and where are the questions that have to be answered so that, in fact, you do have the baseball bat to go after these companies that are--it is not right. And this is not going to be the last hearing, because we don't have the information that we need to proceed.

So I would like to get just--I know my time is expiring, but we would like to get a commitment from you that, in fact, you will be totally responsive to the questions that are asked by Republicans and Democrats so that we can figure out where this train got off the track so that we can put it on and we can assure every person in this country that, in fact, the FDA is working as it should.

And we shouldn't have to hear the stories that we did earlier this morning with Mrs. Lovelace and our constituents, whatever State that they are in. And I would like to get that from you and just assure you that we are not--this is not a one-time deal. We are going to get to the bottom of it.

Ms. Hamburg. You have my absolute commitment that we will continue to work with you and all of your requests for additional information.

You have also touched on a very important point that I want

to underscore, though, which is that we have responsibilities for oversight of manufacturers and drug facilities in this country and around the world, but our authorities to provide oversight of drug manufacturers is very different than our authority to oversee compounding pharmacies, which are, in fact, exempted from important aspects of FDA law.

And there is, you know, this disconnect between different legal requirements in different parts of the country, as well. We have ambiguous, fragmented, unclear, and contested authorities in this particular realm of pharmacy and drug manufacturing practice.

And that is what our opportunity is now and what our responsibility, I think, is, to work together to really create new legislative authority that defines the best approaches, that gives us the broader authorities that we need to address this growing arena of what we call ``nontraditional compounding'' that involves larger volume, more complex products, including sterile products, and broader distribution, potentially putting more patients at risk.

And there are gaps in the oversight authorities of the States, who have primary responsibility for overseeing compounding pharmacies, and the FDA. And we need to make sure that we have a seamless system that protects patients.

Mr. Stearns. The gentleman from California, Mr. Waxman, is recognized for 5 minutes.

Mr. Waxman. Thank you, Mr. Chairman.

I want to commend Chairman Upton for his statements and his questions because I think this committee needs to respond on a bipartisan basis.

And I think we need to correct the law, and we ought to try to do it before we leave at the end of this year for this simple reason: When you get into the next year, some of these interest groups are going to gear up to stop legislation. They will say that we really don't need to have the FDA look at these compounders. FDA regulates the manufacturers, but the compounders are going to be regulated at the State level.

Now, you are being criticized, Dr. Hamburg, as the head of the FDA, for the problems that were primarily the responsibility of the State of Massachusetts. And often we hear on this committee, ``We ought to let the States handle things, not the Federal Government.''

In fact, I want to express some sympathy for you at FDA because you are in a no-win situation. When the FDA asked for more data to determine whether a drug is safe and effective, or takes enforcement action for violations of good manufacturing practices, the agency is accused of being a job-killer, an over-regulator. But now when something terrible happens, we hear that something went wrong and everybody is quick to jump on you for not doing enough.

Now, if we expect you to do more, we better be sure that the statutory law gives you enough authority to do your job, if we want you to do the job and not the State to do the job.

And let me be very critical of the State. The State of Massachusetts dropped the ball. They entered into a consent decree with the company and said--it was a weaker consent decree than they originally started with, and said, oh, you ought to get an independent inspector. So the company hired an

independent inspector. And then the independent inspector came back and said, everything is fine. And then there were questions about whether this was really an inspector that was independent, which is a good thing to keep in mind when we say, let the companies decide who to pick to investigate themselves.

So let's look at what we can do now. How many compounding pharmacies are there in the United States?

Ms. Hamburg. You know, we don't know the exact number because they are not required to register, and so, you know, we are really uncertain. But there are thousands of pharmacies that do compounding. We think that there are about 7,500 pharmacies that do more so-called advanced compounding and about 3,000 facilities that are doing sterile compounding.

Mr. Waxman. Now, compare that to manufacturers where there is no question that you have the jurisdiction to inspect them and to approve their drugs and to recall their drugs. How many manufacturers are there--manufacturing facilities compared to the compounding facilities?

Ms. Hamburg. You know, there are about 5,600 manufacturers that we provide oversight for, including regular inspections. And there is a broader array of facilities that we also oversee in that context.

Mr. Waxman. Well, in 1997 Congress attempted to codify an FDA regulatory system with respect to these compounding pharmacies, but then the Supreme Court later invalidated a part of that law, raising the question of whether the rest of the law is still in force.

Some have argued the FDA still has the ability to cobble together other authorities to act to prevent this tragedy caused by NECC. I don't know if that was a realistic possibility or not. What I do know is that, at the very least, there is a dangerous lack of clarity in FDA's authority here, and we should fix that.

Do you think there is a lack of clarity?

Ms. Hamburg. I think there is an enormous lack of clarity, and I think we should seize this opportunity to address it. We----

Mr. Waxman. What authority and enforcement tools does the FDA need to better enable you at the FDA to take effective action when you discover problems at compounding pharmacies?

Ms. Hamburg. Well, we feel that there needs to be a risk-based framework that enables us to play our critical role in overseeing drugs that are going to the American people. Compounding has an important role in addressing medical needs, and traditional compounding is probably best overseen at the level of the State, though it should always be undertaken by a licensed pharmacist or physician and in accordance with a prescription for a patient for a specific medical need.

Mr. Waxman. We----

Ms. Hamburg. But there is this area of nontraditional compounding, where we think really there needs to be focused attention and new legislation.

Mr. Waxman. Now, all pharmaceuticals that are compounded don't need to be regulated by the FDA, because the traditional way we think of it is a pharmacist putting together a prescription for somebody who has a special need. But now we have an example of a company that is shipping it all over the

country. They are making a drug and they are shipping--they are like a manufacturer of the drug.

What we need from you is very specific authorities that you must have to be able to deal with this. And the second thing we need to recognize is your budget. Because if we give you authority and there are thousands of compounding pharmacies, your agency I can't imagine has the resources to regulate every single one of them, and we need to--you need to rely on the States to complement the FDA's oversight. Is that a fair statement, that you rely on the States?

Ms. Hamburg. That is a fair statement.

And with respect to the authorities, I did outline in the testimony. But we clearly believe that for nontraditional compounders there should be Federal standards that would establish basic safety measures, including sterility controls. Could be enforced by the State or by the FDA, but those need to exist.

Then we need standards, new authorities around registration, so we know who is out there and what they are making. We need to be able to review records----

Mr. Waxman. Let me--you are absolutely right.

And I want to say to Chairman Upton and, for the record, all the members of this committee that we need to get this information. We have to get the right balance. We ought to do it before we leave at the end of the year and make it very clear that we are not just saying, ``You are at fault, you are at fault, somebody else is at fault.'' We are going to be held responsible, as Members of Congress, to make sure the law is clear and that the agency has the ability and resources to do the job that everybody expects you should have done. And we want to make sure that you are able to do it.

Thank you, Mr. Chairman.

Mr. Stearns. The gentleman's time has expired.

The gentleman from Texas is recognized for 5 minutes.

Mr. Barton. Thank you, Mr. Chairman.

I mean, we have a tragedy of significant proportions here. Thirty-two people have died; probably more will. We have a bipartisan investigation before this subcommittee. And we understand that, you know, business as usual is not acceptable.

Having said that, apparently the FDA has decided this is something that they can use to be able to get more authority to regulate or inspect certain transactions that compounding pharmacies do. If there really is a lack of regulatory authority at some level, then that is a legitimate policy recommendation. But if there is not a lack of regulatory authority in existence in State and Federal law right now, then it is unnecessary.

And my first question is to both Dr. Hamburg and Dr. Smith. Are you all both stating that under current State and Federal law neither the State nor the FDA had the authority to seize these drugs or to shut this company down?

Ms. Hamburg. I think it is important to understand----

Mr. Barton. I want a--I don't need a long--I think it is important. If the State of Massachusetts doesn't have the authority and the FDA doesn't have the authority, that is one thing. But we have a warning letter, 2006, issued by the FDA. Now, this is before you were the Commissioner. It says,

``Failure to promptly correct these deviations may result in additional regulatory action without further notice, including seizure or injunction against you and your firm.'' So, in 2006, in the FDA's warning letter, it was the thought at that time that the FDA had sufficient authority.

And Dr. Smith, on behalf of the Massachusetts--she has only been on the job 3 weeks, so we can't hold her liable for what happened, you know, 10 years ago, 6 years ago, 7 years ago. But I don't think there is any question that if Massachusetts felt there was a violation, they had the authority to shut it down.

So, you know, I think we ought to work on using the authority that we have, as opposed to trying to get additional authority at the Federal level.

The FDA went in and inspected this particular company on at least two different occasions and, as far as I can tell, other than issuing one warning letter, didn't do anything at all.

Ms. Hamburg. The truth is that in the initial inspections, we worked very closely with the Massachusetts Board of Pharmacy, which has the responsibility for licensure and oversight on a day-to-day basis of compounding pharmacies, but----

Mr. Barton. So, again, go back and answer my question.

Ms. Hamburg [continuing]. We acted to make sure that the contaminated product was recalled and not continuing to put people at risk. Our first priority was----

Mr. Barton. So you are saying the FDA did have the authority or did not have the authority?

Ms. Hamburg. We worked closely with Massachusetts, who had----

Mr. Barton. Can you ever give a straight answer to the question?

Ms. Hamburg [continuing]. The primary responsibility for the oversight of that facility.

Mr. Barton. Either you do or you don't.

Ms. Hamburg. I think, you know, what is very clear is that----

Mr. Barton. What is very clear is that you don't want to answer the question.

Ms. Hamburg. No, it is complicated, and that is reflected here.

But the responsibilities are different. What FDA has clear and strong responsibility for and oversight of----

Mr. Barton. Let me ask Dr. Smith.

Ms. Hamburg [continuing]. Is drug manufacturers.

Mr. Barton. Dr. Smith, does your State----

Ms. Hamburg. These are held to a different standard. Compounding pharmacies are----

Mr. Barton. Does your State agency have the authority to shut this company down if you see a clear violation of the law, yes or no?

Ms. Smith. Yes, it does.

Mr. Barton. OK.

Ms. Smith. And, in fact, we----

Mr. Barton. Thank you. Now, if you----

Ms. Hamburg. But the State of Massachusetts----

Mr. Barton. At least you got----

Ms. Hamburg [continuing]. Has the oversight responsibility

for compounding pharmacies on a day-to-day basis. FDA has a different set of authorities.

And the challenge is that these authorities, as evidenced by that map, are fragmented. And what enforcement actions we can take have to be seen through different lenses in different parts of the country.

Mr. Barton. All right.

Ms. Hamburg. We don't have clear----

Mr. Barton. I am going to try one more time, Dr. Hamburg. Under current law, does the Food and Drug Administration of the United States of America have authority over adulterated drugs?

Ms. Hamburg. We have authority over adulterated drugs, and----

Mr. Barton. Thank you.

Ms. Hamburg [continuing]. We can take actions in relation to that.

Mr. Barton. OK.

Mr. Dingell. May the Congressman from Texas have 1 additional minute? And I would ask that he would yield to me.

Mr. Stearns. By unanimous consent, so ordered.

Mr. Barton. And I would be happy to yield to my good friend, the gentleman from Michigan.

Mr. Dingell. I thank my friend.

Commissioner, two agencies here have dropped the ball. The Massachusetts agency has had to fire its head because it didn't do its job. Your agency--and I don't want you to be defensive; I just want you to recognize a hard fact. Your agency did not use your power to define who is a manufacturer. Here you have an agency that is--that in just one has sold over 17,000 doses in something like 23 States.

Don't you have the authority to define who is a manufacturer and who is a compounder? And if you do, why didn't you do it?

Ms. Hamburg. The problem is that the current legal regulatory framework says either you are a compounder or you are a manufacturer, and there, in fact, is----

Mr. Dingell. And you may define both, may you not? You have that authority, and you did not do it.

Ms. Hamburg. I----

Mr. Dingell. And I thank the gentleman for yielding.

Ms. Hamburg. The concern, though, is that if it is all or nothing that way, then these facilities, if they were defined as manufacturers----

Mr. Dingell. Commissioner, we are trying to solve the problem. This is not an issue of where you are here to defend yourself. If you choose to do that, you are going to have a very hard time in this committee. We do not tolerate that kind of foolishness, and I would assure you that you are putting your head in the noose.

I would urge you to just cooperate with us and with my good friend and give us the answers that we need----

Mr. Barton. All right. Now----

Mr. Dingell [continuing]. So that you can address your problems----

Mr. Barton [continuing]. If I can reclaim the time I no longer have----

Mr. Stearns. Just to recognize where we are, we had a

unanimous consent to give Mr. Dingell 1 minute, and the time now belongs to Mr. Barton.

Mr. Barton. I am just going to----

Mr. Stearns. If you would finish up and we will move on to----

Mr. Barton. Yes, I will be quick.

I want to be explicitly clear. If there really is a regulatory gap--based on the record that I have reviewed, I don't believe there is. But if there is, I suggest there is a bipartisan coalition on this subcommittee and full committee that will move legislation to correct it.

If, however, there is no regulatory gap, I also think there is a bipartisan coalition on this subcommittee and full committee to work to make sure that the State and the Federal agencies with jurisdiction work together to solve this problem and to prevent it from happening in the future.

And, with that, Mr. Chairman, I yield back.

Mr. Stearns. Yield back.

And I want to thank the dean of the House of Representatives for his taking the initiative to really get the Commissioner to answer the question that both Mr. Barton and myself and others have asked, is whether you have the jurisdiction, and I think the answer is yes.

Ms. Hamburg. No----

Mr. Stearns. We recognize for 5 minutes Mr. Dingell.

Mr. Dingell. I thank you, Mr. Chairman.

Commissioner, I would appreciate ``yes'' or ``no'' answers here.

Do you have sufficient authority to inspect compounding pharmacies, yes or no?

Ms. Hamburg. No.

Mr. Dingell. Would you please submit is to us what authorities you need so that we can see to it that it is done?

Do you have the authority to access all records when inspecting a compounding pharmacy, yes or no?

Ms. Hamburg. No.

Mr. Dingell. Please submit to us the information on what you need so we can see to it that that is given to you.

Do you have authority to require compounding authorities to--rather, compounding pharmacies to register with FDA, yes or no?

Ms. Hamburg. No.

Mr. Dingell. Would you please submit to us the authorities that are needed so that we can address that problem?

All right. Do you have the authority to require compounding pharmacies to report adverse events to FDA, yes or no?

Ms. Hamburg. No.

Mr. Stearns. Would you please submit to us what authorities you need in that area?

You heard earlier my question about whether or not you have the authority to define who is a compounding pharmacy and who is a manufacturer. Do you have authority to do that or not, yes or no?

Ms. Hamburg. Yes, on a very technical level.

Mr. Dingell. All right. If you need some reform of that authority, please submit that information to us.

Ms. Hamburg. We definitely do.

Mr. Dingell. Commissioner, do you have authority to require compounding pharmacies to follow good compounding or something equivalent to good manufacturing practices, yes or no?

Ms. Hamburg. No, we do not.

Mr. Dingell. Would you please submit to us the authority that you require?

Now, this question to both you and to Dr. Smith: Do you have sufficient authority between your agencies, State agencies and the Federal agencies, to assure that you are able to coordinate your authorities and to achieve the necessary controls over both manufacturers and compounding pharmacies?

Ms. Hamburg. I believe we do not.

Mr. Dingell. You do not.

What is your view on that, Dr. Smith? Yes or no?

Ms. Smith. We don't regulate or oversee manufacturing, so----

Mr. Dingell. OK, but can you define a compounding pharmacy so that you can define your authority? We have here something where a major problem fell between the cracks. Please submit the answer to us for the purposes of the record.

Now, again, to the Commissioner, do you have authority to require compounding pharmacies to indicate on the label of their product that the product was compounded and not approved by FDA, yes or no?

Ms. Hamburg. We do not.

Mr. Dingell. Would you please submit the authority--the authority that you need?

Commissioner, it does not sound to me like FDA has authorities to oversee compounding pharmacies, and there is a question of your authority to define who is a compounding pharmacy. Do you have efficient--do you have sufficient authority to oversee compounding pharmacies now, yes or no?

Ms. Hamburg. We do not, no.

Mr. Dingell. OK. Please submit to us your suggestions for that authority to be given.

Do you--would you submit to the committee any additional authorities that I have not been able to define here this morning that we should address to you?

Now, Commissioner Hamburg, your agency is in receipt of two letters dated October 9 and 16, 2012, from my office regarding this situation. When will you submit to us a response to those letters so that we can have that information available to us as the committee proceeds?

Ms. Hamburg. We will get you those responses as soon as possible.

Mr. Dingell. As soon as you can.

Mr. Chairman, with thanks, I return to you 24 minutes.

Mr. Stearns. I think----

Mr. Dingell. One more question, Mr. Chairman. Those two letters, I would ask that they be inserted in the record and the response that will be received by the committee.

Mr. Stearns. We have seen those letters. By unanimous consent, so ordered.

Mr. Dingell. Thank you.

Mr. Stearns. And I thank the gentleman from Michigan.

The gentleman from Nebraska, Mr. Terry, is recognized for 5 minutes.

Mr. Terry. Thank you, Mr. Chairman.

Here--I want to follow through on some of the gentleman from Michigan, Mr. Dingell's questions because I really do think that is at the heart of us trying to figure out where our jurisdiction lies or doesn't lie with the FDA and our role.

So I have toured compounding facilities in my district, which usually are small operations. In the part of a current pharmacy, somebody brings in a prescription that is unique, they compound it, and it is for that patient. That is compounding.

And I don't think the FDA would want--and that is a question for a different day--the jurisdiction to go into every pharmacy that has compounding abilities to make something specific for one of their clients. And that is why that has been reserved, I assume, in those discussions, the gentlelady from Colorado, of why it was put in the States' hands that are best able to do that.

So now when we focus on the New England Compounding Center, it may have called itself ``compounding center,'' but it was a large manufacturing. We know that through its past violations that have come to the attention of both the State pharmacy board and the FDA in the past. So we then have a 2011 incident in Denver where pallets of a drug was found; a Colorado board of pharmacies issues a cease and desist. So now what we have is mass manufacturing of a specific drug for nonspecific people. To me, that is the definition of ``manufacturing.''

So, Ms. Honorable Hamburg, is the issue, then, that the definition of ``manufacturing'' within that bill isn't clear enough for the FDA? Because it seems pretty clear, if you are mass producing, you are sending it into interstate commerce and it is not for a specific patient, that that is not compounding, that is manufacturing.

Ms. Hamburg. I think that this has been an evolving industry and that we do have a problem that existing law and authority is----

Mr. Terry. What specifically----

Ms. Hamburg. It is on or off----

Mr. Terry. Let me interrupt you, since you talk over us.

I am looking for the specifics in the law that say that there is lack of clarity on the definition of ``manufacturing.'' Because that seems to be the hook that you are putting your hat on. Can you specify in the act that we have to tighten the definitions?

Ms. Hamburg. Currently, as we have discussed, there is huge disagreement about the FDA authorities, and the courts have split on the interpretation of authorities for compounding----

Mr. Terry. Will you define the parts of the statute that we need to focus on regarding tightening the definition of ``manufacturing''?

Ms. Hamburg. The problem is that, with this evolving industry, there is a gray area. If we would be to regulate the thousands of compounders----

Mr. Terry. That is a great speech. Can you refer me to the part of the statute that we need to focus on, yes or no?

Ms. Hamburg. I am sorry, could you repeat----

Mr. Terry. Refer me to the appropriate part of the statute that lacks the clarity of which you complain.

Ms. Hamburg. The FDA has the authority to act against----
Mr. Terry. Manufacturers.
Ms. Hamburg [continuing]. Manufacturers.
Mr. Terry. And this is generally manufacturers----
Ms. Hamburg. We have the oversight of drug manufacturers, and with that comes a set of activities----
Mr. Terry. All right.
Ms. Hamburg [continuing]. That do not apply to compounders, including the----
Mr. Terry. So you will not refer me to a specific section of which you feel lacks clarity.
One last question for Dr. Smith.
This is very frustrating, madam.
Dr. Smith, you are in a really tough place, and you have done a great job. You have presented well today. But I am very curious. With all of the knowledge that was brought to the State board--a colossal failure here. You said you are looking into that and putting the pieces together. I am just curious, is there any evidence of a special relationship between the State board and this manufacturer? Because it seems like somebody is covering for somebody.
Ms. Smith. Well, we are as concerned about the missed opportunities as you are. And there are numerous, numerous episodes of that. We are in the process, as I said, of reviewing just that through interviews and through the exhaustive document reviews that we are doing and reviewing the documents that we have produced for this committee. It is, you know, thousands and thousands of pages.
So I can't--I don't know the answer to your question, but we are trying to----
Mr. Terry. Well, I appreciate that you are looking into that.
Just the last 5 seconds, Madam Honorable Hamburg. Getting your testimony at 1:30 a.m., most of us are sleeping then, so I guess the whole purpose was to not let us see in advance your testimony.
I yield back.
Mr. Stearns. The gentleman yields back.
The gentleman from Massachusetts, Mr. Markey, is recognized for 5 minutes.
Mr. Markey. Thank you, Mr. Chairman.
Ms. Hamburg, I have introduced legislation to give the FDA authority to define which compounding pharmacies should be required to register as manufacturers. Would you support that?
Ms. Hamburg. We think it is very important that we have additional legislation in this area and that compounders, in fact, register and that it can be defined, what they are doing, what they are manufacturing, and what the appropriate regulatory oversight would be.
Mr. Markey. I have introduced legislation to give the FDA authority to require compounding pharmacies to compound safe drugs using safe practices. Would you support that?
Ms. Hamburg. I do support that.
Mr. Markey. I have introduced legislation to give FDA authority to conduct the same inspections and request the same documents as it can from manufacturers. Do you support that?
Ms. Hamburg. It is enormously important that we have the

authority to go in and be able to do full inspections and review documents, collect samples, et cetera.

Mr. Markey. I have introduced legislation that requires compounding pharmacies to submit reports of adverse reactions or safety problems to the FDA. Do you support the FDA having that authority?

Ms. Hamburg. Yes. It is currently a gap, that adverse events are not required to be reported from compounding pharmacies.

Mr. Markey. And I have introduced legislation to require compounded drugs to be labeled. Do you believe that that authority should be given to you?

Ms. Hamburg. Yes, we do.

Mr. Markey. And I might say, the legislation also allows traditional compounding pharmacies, those which are just doing individual doses to individual patients, to continue to stay under State jurisdiction. Do you agree with that?

Ms. Hamburg. Traditional compounding, one patient, one prescription----

Mr. Markey. Yes.

Ms. Hamburg [continuing]. Should be overseen by a licensed physician or pharmacist, but it does not require the FDA oversight.

It is this nontraditional compounding area where the volume is larger, the distribution is larger, the products are more complex, where we think we lack the authorities that we need. And we appreciate that you are introducing legislation, and we will work actively with you----

Mr. Markey. Thank you.

Ms. Hamburg [continuing]. In order to an achieve the important goal.

Mr. Markey. I think it is critical, given today's hearing, given what we have heard from the witnesses, the pain that it has caused, the regulatory black hole that obviously has to be closed, that we pass legislation that gives you these authorities----

Ms. Hamburg. I agree with you.

Mr. Markey [continuing]. So that children will have to look to the history books to find that there ever was such a catastrophe as is being suffered by hundreds of families across the country right now. And so I just hope that we can move quickly on legislation to give you that authority because I think you are the cop on the beat and we have to make sure that you have the authority which you need in order to enforce the law.

And, Dr. Smith, I want to commend you and Governor Patrick for the decisive manner in which you have responded to this tragedy. You have undertaken an aggressive investigation and held the companies involved and some members of your staff accountable and put in place stringent emergency regulations for compounding pharmacies in Massachusetts.

We have learned that this tragedy was enabled by a regulatory black hole that allowed a drug manufacturer, NECC, to masquerade as a pharmacy, producing massive amounts, quantities of drugs with little or no Federal oversight, and able to sell these vials all across the country to dozens of States without full Federal regulation.

And there were complaints that had been reported as long as 10 years ago. Starting in 1999 with the first complaint, State regulators repeatedly failed to take strong action, such as withdrawing NECC's license in 2006. The State even waived the company's proposed probation as long as it got a clean bill of health from an independent evaluator. But when that same independent evaluator was convicted of selling unsafe medical sterilization equipment that blinded 18 patients, Massachusetts did nothing to make sure the clean bill of health that the New England Compounding Center had received was reexamined.

Dr. Smith, have you been able to determine why those decisions were made back then through interviews with the staff that were there at that time?

Ms. Smith. No, we have not. We have done interviews, as you allude to, and we have not been able to really understand why they made those decisions. In retrospect, clearly there were missed opportunities for the Board of Pharmacy, as you point out, in 2006 to take decisive action, and it did not. And we are trying to understand that, but we don't at this point.

Mr. Markey. Are all of those individuals' emails and other documents from that period available for review?

Ms. Smith. Yes. We have--we produced for this committee thousands of--thousands of pages of emails. And those are all being reviewed.

Mr. Markey. Is it possible that some of those emails and documents have been destroyed in the period of time from 2006 and prior to today?

Ms. Smith. Well, I am not--I wouldn't be sure of that. I can tell you that the numbers of emails from the earlier, prior years are far fewer than what we have been able to obtain more recently.

Mr. Markey. So Massachusetts is, in the very near future, going to have the strongest compounding pharmacy regulation in the country. But that does not protect us, does it, from other States having weak laws, which could then sell compounded drugs into Massachusetts----

Ms. Smith. That is correct.

Mr. Markey [continuing]. Or the other 49 States?

So you just heard the list of powers which I asked Dr. Hamburg if she would support being given to the FDA. Do you support giving the FDA those same powers so that they can be the national cop on the beat to protect against one State becoming the place where a rogue compounder then terrorizes and harms the rest of the country?

Ms. Smith. Absolutely.

Mr. Markey. I thank you. I thank all of you for your service.

And I thank you, Mr. Chairman.

Mr. Stearns. I thank the gentleman and recognize Dr. Burgess for 5 minutes.

Mr. Burgess. I thank the chair for the recognition.

Dr. Hamburg, again, thank you for being here today.

Let me ask you, you made a statement a minute ago in response to another Member's question that you favored a risk-based system; is that correct?

Ms. Hamburg. We do favor a risk-based----

Mr. Burgess. Let me just stop you for a second, because, I

mean, this country was--company was bad news from the day it started back in the '90s. They, as is my understanding from looking at the materials provided to us, they shipped preprinted prescription forms to various clinics around the country in clear violation of what they should be doing.

And then you have--the FDA, not you, but the FDA has assembled a 10- or 15-year history of repeated violations and areas where this company has shown itself to be unsafe. So if you want to have a risk-based system, this company is too risky. You can't risk it. Don't do a risk-based system for this company. It is through. And, in all honesty, it should have been terminated by the FDA, multiple branch points along the way--2002, 2004, 2006, 2008. We see the documents. It should have happened.

Now, I guess, listening to your testimony today, I must be given to believe that what you have been doing is collecting the data set so that what Congress finally passed a law to allow you to prevent this from happening you would then prevent it. Is that what I am understanding? That you lack complete and total authority to do anything at all even though you saw this stuff happening?

Ms. Hamburg. You know, we worked very hard when the first problems at NECC were identified with the State to address them aggressively. But our authorities around compounding pharmacies are unclear, limited----

Mr. Burgess. Yes, let me stop you.

Ms. Hamburg [continuing]. And untested.

Mr. Burgess. We have been down this road before----

Ms. Hamburg. We need----

Mr. Burgess [continuing]. And we are not buying it. We are just not buying it, Dr. Hamburg, in all honesty.

You have an evidence binder in front of you. Tab 15, look at it, if you will. It is a letter dated October 31st, 2008. We have heard other people reference a 2006 letter where the FDA, the FDA, in writing to this compounding pharmacy, say, ``Failure to do so may result in an enforcement action, including a seizure of the firm's products and/or an injunction against the firm and its principals.'' That is pretty strong language.

Now, you lacked the authority to do anything and yet you sent a letter like this? Was this letter sent in error? You really didn't have that authority, and it was an empty threat; is that what I am to understand?

Ms. Hamburg. As, you know, was pointed out, I was not present at the FDA at the time, and I cannot speak to all of the issues. But there--clearly, there was an effort to assert authority----

Mr. Burgess. Well, let me just ask you----

Ms. Hamburg [continuing]. Around an issue that was very different than the issue about sterile compounds----

Mr. Burgess. OK. But this letter was issued in error; is that what I am to understand? It was an error, that the FDA sent this, even though it was a previous administration, a previous Commissioner?

Ms. Hamburg. There were--in 2004, the FDA was asked to take a look at an issue that involved a specific product, Trypan Blue, and whether or not NECC was making it inappropriately.

Mr. Burgess. OK. With all due respect here--and our time is limited. I don't mean to be rude, but we really have to pursue this.

Did you, did anyone at the FDA, previous Commissioner, previous administration, did anyone get a legal memo from your legal department saying, ``Hey, you didn't have the authority to do that, so you better back off''? Is there such a memo in existence?

Ms. Hamburg. There was a lot of internal discussion. The courts were split on what our authority----

Mr. Burgess. So was there a memo delivered from the Commissioner?

Ms. Hamburg. Well, at that time, there was ongoing litigation, and----

Mr. Burgess. May we on the committee have access to those internal memos that said you didn't have the authority to write that letter?

Ms. Hamburg. That isn't what I said, and I apologize if it came across that way. What I was saying was that an inspection was done in response to a specific complaint, and then, with respect to the actions taken, there was ambiguity in the law, ongoing litigation----

Mr. Burgess. Yes, but there is no ambiguity.

Ms. Hamburg [continuing]. Discussions within FDA, as I understand it, about----

Mr. Burgess. OK, let me try it from another perspective, if I could.

Ms. Hamburg [continuing]. What enforcement could be used to take action.

Mr. Burgess. We all saw on television the company being raided, the computers being seized. Did you do that and you didn't have the authority to do that?

Ms. Hamburg. In the--I mean, you are asking me about one specific question that had to do with the warning letter, which is a very discrete and different problem than what we are talking about----

Mr. Burgess. But you assert an authority which you are now telling us you don't have in that letter. Now----

Ms. Hamburg. I think you just need to look at the map and see that the authority that is used to oversee compounding pharmacies is very fragmented. We have different court decisions applying different legal regulatory frameworks to different parts of the country that cannot serve patients well.

We need to have a strengthened and clarified legal regulatory authority that gives us some of the additional authorities over----

Mr. Burgess. OK. Once again, let me just ask you as straightforward and simply as I can, do you have the authority to regulate the manufacturer, or if a compound is--of the manufacturer of these compounds or if the drug is adulterated in some form? Do you have that authority, as it exists today?

Ms. Hamburg. We have many more authorities over drug manufacturers than compounding pharmacies. And that limits our ability to effectively ensure the safety and quality----

Mr. Stearns. Dr. Hamburg----

Mr. Burgess. Well, again, let me just ask it in the simplest way that I can. How many companies are out there

labeled as compounding pharmacies that ship 17,000 doses of sterile, preservative-free steroids every year?

Ms. Hamburg. The problem is that compounding pharmacies are not required----

Mr. Burgess. How many? The question is, how many?

Ms. Hamburg [continuing]. To register with us. We don't know how many compounding pharmacies are, in fact, engaging in those kinds of practices.

What we do know is that the industry, though, has evolved and that there are an increasing number of nontraditional compounders who are acting, for example, with hospitals and clinics----

Mr. Burgess. Look----

Ms. Hamburg [continuing]. Are outsourcing to them----

Mr. Burgess [continuing]. We heard testimony from the widow of a victim. And you could tell that there was some bitterness in her voice against the company--or, the clinic that had provided the steroid injections. ``How could they buy it from someone if they weren't sure?''

But, you know, I am a doctor, you are a doctor, Dr. Smith, you are a physician. I mean, you take a vial off the shelf, you make some assumptions as to its potency and its sterility. In this country, we stipulate that, because you have done your job at the FDA, we don't have to come and ask additional questions before we administer that to a patient.

Now you are telling me that that is not the case and that the FDA lacks the authority to assert that the safety and effectiveness of those medicines that are coming off the shelf is, in fact, valid?

Ms. Hamburg. We have the authority with drug manufacturers to oversee the safety, efficacy, and manufacturing quality.

Mr. Burgess. Correct.

Ms. Hamburg. We do not have----

Mr. Burgess. And if you are making 17,000 doses of sterile, preservative-free, injectable steroids every year, you are a manufacturer. There is no other word for it.

Mr. Stearns. The gentleman's time has expired.

Mr. Burgess. I thank the gentleman.

Mr. Stearns. Let the record show, Dr. Hamburg, he asked you a question. You are under oath. You have an obligation to answer ``yes'' or ``no.''

Ms. DeGette. She tried to answer----

Ms. Hamburg. I was attempting to, and----

Mr. Stearns. And let the record show----

Ms. Hamburg [continuing]. I am sorry if I did not.

Mr. Stearns [continuing]. That Dr. Burgess asked you a question time and time again, the same question, and you would not answer ``yes'' or ``no.''

Let me recognize----

Ms. Hamburg. We do not have the authority over compounding authorities----

Mr. Stearns. That is--Dr. Hamburg, we understand that.

Ms. Hamburg [continuing]. That we have over drug manufacturers.

Ms. DeGette. Wait a minute.

Mr. Stearns. The gentlelady from Florida, Ms. Castor, is recognized for 5 minutes.

Oh, Ms. Schakowsky. Oh, I am sorry. Yes, welcome.

Ms. Schakowsky. This is for Dr. Smith.

In the aftermath of this tragedy, we have learned some troubling facts about the Massachusetts Board of Registration and Pharmacy and how it dealt with NECC in the past. And it raises some questions about whether the board was too close to NECC and whether the board did enough to prevent conflicts of interest from affecting its decisions.

So I wanted to ask you, Dr. Smith, about Sophia Pasedis, one of the members of the board. I understand she is gone now; is that true?

Ms. Smith. No. We have asked her to resign, but she declined.

Ms. Schakowsky. So how long has she served on the board?

Ms. Smith. I don't have that in front of me, but it has been for several years. She was there in the previous administration.

Ms. Schakowsky. And what is her affiliation with NECC or its sister companies?

Ms. Smith. She had previously worked for NECC. I am sorry--she started in the summer of 2004. She had previously worked for NECC and then subsequently went to Ameridose, a company that was also owned by Mr. Cadden.

Ms. Schakowsky. So I understand that she was actually vice president of regulatory affairs and compliance at Ameridose.

Ms. Smith. Yes. And she is the pharmacy of record there.

Ms. Schakowsky. Did Ms. Pasedis adequately recuse herself from board actions related to these companies?

Ms. Smith. In our review of the minutes of the board meetings, it is clear that on several occasions there is a specific indication that she did recuse herself. However, there are some minutes that don't--that are silent on the issue, don't say either way. And because of that, the fact that it was unclear she appropriately recused herself--although in interviews she declares that she did--because of the lack of clarity, we asked her to resign, which, as I said, she declined.

Ms. Schakowsky. So I am glad that you attempted to take action to remove her, but there is still a lot of questions about whether her role on the board during much of the time when Massachusetts was receiving complaints softened the actions of the board that the board was willing to take against NECC.

In 2004, after first identifying significant problems at NECC, the board proposed a tough consent agreement with real sanctions. But something happened in the interim, and the consent decree that was actually signed in 2006 was much weaker than in the initial proposal.

Do you know how this happened and why the board proposed weaker penalties even after they had received additional reports of problems at NECC?

Ms. Smith. We don't know how that happened, and, as I mentioned, we are very interested and have been attempting to find that out. Our interviews with board members about that precise issue have been--have not yielded definitive information. Most simply state that they don't recall.

Ms. Schakowsky. So one of the problems with the 2006

consent agreement was that it required NECC to be independently audited but then let NECC have significant input into who its independent evaluator would be.

So, Dr. Smith, did NECC participate in the selection of PSI as its independent auditor--evaluator?

Ms. Smith. Well, we are unsure. We have been reviewing the records to, in fact, try to determine who did make the final decision regarding who that independent evaluator should be. And it is unclear, from the documents that we have found, who did do that.

Ms. Schakowsky. And is it common for a party to help select its own evaluator?

Ms. Smith. I can't speak to whether or not it was common. You could certainly imagine that that would be problematic. But we haven't been able to determine who, in fact, chose the evaluator.

Ms. Schakowsky. Is it still the practice?

Ms. Smith. Well, it would be--currently, I am not aware of any current actions that are involving an outside evaluator. As we proceed, as I mentioned, we are really looking at both the best practices around other States for the Board of Pharmacy, and so that would be the kind of thing we would include.

Ms. Schakowsky. Well, let me just say, at the time that PSI was selected to act as an independent evaluator, one of its executives, Ross Caputo, was facing trial for defrauding the FDA and selling unapproved sterilization equipment to hospitals that caused blindness in patients. And he was later convicted.

So in 2006 your agency sent a letter to NECC telling them that they had ``satisfactorily completed,'' unquote, the conditions of the consent agreement based on NECC's compliance with the follow-up actions identified in PSA's audit report of the company; is that correct?

Ms. Smith. That is correct.

Ms. Schakowsky. So were any of the Massachusetts Board of Registration and Pharmacy staff aware of Mr. Caputo's Federal conviction when they found NECC had satisfactorily completed PSI's recommended actions?

Ms. Smith. As far as we can tell through our interviews with staff and the board members, they were not made aware of the fact that the primary evaluator, Mr. Caputo, had, in fact, been convicted of those Federal crimes. The staff were aware, but, as I have mentioned, and shockingly so, they did not share that information with the board.

Ms. Schakowsky. Well, you know, we have turned up a number of problems, but, one, it seems that the NECC was too close to the board and its members, and it seems like the board was more interested, maybe, in protecting pharmacists than in protecting consumers.

We have a lot of work to do, but it seems like that some of the solutions that we have laid out, at least on the Federal level for the FDA, are fairly clear. And I am hoping that at the State level, as well, that these problems will be--you will get to the root of them.

Thank you.

Mr. Stearns. The gentlelady's time has expired.

The gentleman from Pennsylvania, Mr. Murphy, is recognized for 5 minutes.

Mr. Murphy. Thank you.

Dr. Smith, in your testimony, you had stated that you have uncovered a number of problems where PSI executives and others did not provide information to people. You said you have found no evidence to indicate the executive directors or staff attorney of the board provided crucial information to the board, and yet the board had to vote on something without that information. Am I correct?

Ms. Smith. That is right.

Mr. Murphy. And you have given a number of other examples of a breakdown within the structure and have taken action toward people when you found that they were not properly informing or following the rules?

Ms. Smith. That is correct.

Mr. Murphy. OK. Is there anything also within the laws, as you understand it, that you have the authority within Massachusetts, are required, to pass information up to the FDA on any of these problems that occur?

Ms. Smith. There is nothing in our practices or our regulations that I am aware of that requires that kind of information share.

Mr. Murphy. Do you do it anyway?

Ms. Smith. Certainly, since this investigation or this episode has begun, we have worked in partnership with the FDA and, in fact, have done all of the inspections together. That is an area, as I mentioned, when we move forward to determine what sorts of policies we should have about information sharing----

Mr. Murphy. Thank you.

Ms. Smith [continuing]. Whether it should be required as opposed to on a case-by-case basis.

Mr. Murphy. It is helpful internally to identify those breakdowns, too.

Ms. Hamburg, is there someone at the FDA who routinely reviews State actions and communicates with them from your level down to the States when there are problems occurring? Is there anybody who reads or reviews anything with the States at all right now?

Ms. Hamburg. There is not a system in statute----

Mr. Murphy. But is there anybody who does that?

Ms. Hamburg [continuing]. Or in practice where there is that kind of back-and-forth communication on a routine basis. When there is a serious problem, as occurred in this case, you know, we mobilize into action very quickly. We have----

Mr. Murphy. Who is it that is mobilized in the FDA to then work with States?

Ms. Hamburg. Different components of FDA, depending on the nature of the problem.

Mr. Murphy. Is there a particular person?

Ms. Hamburg. We have district offices, and they are sort of the first line in terms of identification of a problem----

Mr. Murphy. I am just trying to get some specifics here.

Ms. Hamburg [continuing]. And responding----

Mr. Murphy. I am trying to lay out here that Dr. Smith did a thorough internal review and found a number of breakdowns that people weren't communicating with one another.

I am trying to find out within the FDA--regardless of

regulations, obviously if someone with the FDA was talking to the States, someone has the authority to talk to States. And I am trying to find out if you have identified structural changes needed within the FDA to make sure you are communicating within FDA that information is coming to your desk for review. Have you made any of those changes or reviews?

Ms. Hamburg. I think part of the issue here is there are not formalized systems. There certainly are opportunities to improve communication. But it also is a broader issue, that compounding pharmacies----

Mr. Murphy. Hold on. Really, I am trying to help.

Ms. Hamburg. Uh-huh.

Mr. Murphy. And you are obfuscating.

Dr. Smith, very cogent leadership, says, if there are problems, identify the problems, we went after the problems. I am just trying to find out, do you even have--you don't have to wait for authority to find out within the FDA who can have the authority to review these things. Do you have it, yes or no?

Ms. Hamburg. We--well, I am not sure what authority you mean.

Mr. Murphy. Well, the authority to review if there are problems with the States and manufacturing, et cetera.

Ms. Hamburg. We don't always get the reports is the issue. When we do get the reports, then we have our district offices and Office of Regulatory Affairs----

Mr. Murphy. OK. Have you met with those people since from the district offices to review----

Ms. Hamburg. Yes.

Mr. Murphy. OK. Thank----

Ms. Hamburg. We have been working very closely with them. And, you know, every day there are issues that involve our working with States----

Mr. Murphy. Well, let me ask another area, too, in terms of identifying people. In terms of dealing with the definition of ``compounding pharmacy'' versus ``manufacturer,'' who within the FDA is responsible for defining that?

Ms. Hamburg. Well, the--it is not just in FDA. It is Congress----

Mr. Murphy. But who is it that--who is the keeper of the definition that when you have a question----

Ms. Hamburg. But our--our----

Mr. Murphy. Who?

Ms. Hamburg. Our chief counsel's office is----

Mr. Murphy. Chief counsel. Have you reviewed with chief counsel the definition of ``manufacturing'' versus ``compounding''?

Ms. Hamburg. I think that everyone agrees that, at the present time----

Mr. Murphy. I didn't ask you that.

Ms. Hamburg [continuing]. That the law is not----

Mr. Murphy. Please. Please, please, please.

Ms. Hamburg [continuing]. Clear on this.

Mr. Murphy. Please. I want to know, have you reviewed with someone--you said chief counsel--the definition of ``compounding'' versus ``manufacturing''? Have you reviewed that with someone? When did that take place?

Ms. Hamburg. You know, we have had many discussions on it,

but the problem is----

Mr. Murphy. So has someone reviewed with you a definition of ``manufacturing'' versus ``compounding''?

Ms. Hamburg. You know, I think that, really, you know, unfortunately, there is not a clear----

Mr. Murphy. Yes, there is. Because in your authority--if you are telling us the crux of your testimony today is you don't have authority under manufacturing, you therefore must have met with someone who told you what the definition of ``manufacturing'' versus ``compounding'' is. I would like to know who that is. Or is it you?

Ms. Hamburg. Well, you know, I really do think this is a broader issue. I know that you are frustrated by my answers, and I am sorry that I can't just give ``yes'' or ``no,'' but this is a very complex issue. The courts of our country are split on these issues.

Mr. Murphy. Ma'am, that is not complex. Complex is the life that the 32 victims' families have now. That is complex. What you have to do is easy, ma'am. Children growing up without parents, people without a spouse, living that lonely life, that, I submit to you, is complex.

Leadership is easy if you are willing to accept it. And you are not. Dr. Smith took leadership. She went in and cleaned house and identified problems.

What you are telling me is all this smoke and mirrors, that you don't have authority. Go look in the eyes of the victims, and try and comfort them with that. Ma'am, that doesn't work.

I am asking you a simple question, as everybody else has here. And you can't even tell us if you have talked to someone to come up with a definition of ``manufacturing.''

Ms. Hamburg. No, I have told you we have been working very, very hard----

Mr. Murphy. Tell us who----

Ms. Hamburg [continuing]. To try to apply the authorities we have to an evolving industry and situations where we do not have the authorities we need. We don't even have registration of the compounding facilities to know who they all are. We cannot review the record. There are no Federal standards to which the compounding pharmacies are held. And the courts have not----

Mr. Murphy. You should be able to provide us with a definition.

Ms. Hamburg [continuing]. Been able to agree on what is the legal regulatory framework for examination of these problems and enforcement actions.

I care deeply about the patients and the families. The mission of the FDA is to promote and protect health. We are as frustrated as you are that we don't have the authorities and the resources----

Mr. Murphy. Then just tell us the definition, ma'am. We will move from there.

I yield back. Thank you.

Mr. Burgess [presiding]. The gentleman's time has expired.

The chair now recognizes the gentlelady from Florida, Ms. Castor, 5 minutes, for your questions, please.

Ms. Castor. Thank you very much.

And I appreciate all of us coming together to focus on what

we can do to prevent tragedies like this from ever happening again.

Now, I do think it is clear that there is great ambiguity in the law. FDA--the law with regard to compounding pharmacies was last written in 1997; it is out of date. And from my colleague from Texas, there is ambiguity here, great ambiguity. And it has been made even more convoluted due to these court cases. And I wish we would bring this map up on the screen, as well, so folks watching outside this hearing room could see it.

See, in 1997 the Congress passed the FDA Modernization Act. That law contained a provision, section 503(a), which dictated the circumstances under which compounded drugs were new drugs and subject to FDA regulation. In that law, Congress explicitly exempted compounders from oversight and regulation as manufacturers. So I know that is what they are struggling with in trying to answer questions here.

Then the courts stepped in. And this is where I would like to follow up on Mr. Terry's question of you, Dr. Hamburg, about exactly which section of the act lacks clarity and his request that you direct him to it. We are talking here about the entirety of section 503(a), aren't we?

Ms. Hamburg. Well, 503(a) applies in some areas of the country and not in other areas of the country, which is a very challenging situation----

Ms. Castor. Yes. Let's look at the map.

Ms. Hamburg [continuing]. In terms of our ability to be as effective as possible.

Ms. Castor. Because in 2001, the ninth circuit, whose jurisdiction is the Western States, those red States, ruled that the advertising component of 503(a) was unconstitutional. And then they said that the rest of 503(a) is void because it is inextricably tied to the advertising component.

Then, a few years later, in 2008, the fifth circuit court, the blue States there to the south, whose jurisdiction includes Texas, Louisiana, and Mississippi, ruled that the unconstitutionality of the advertising restrictions did not affect the rest of 503(a). And, unfortunately, the United States Supreme Court did not speak to break the tie to provide clarity.

So, Commissioner Hamburg, what has been the impact on FDA in its regulation of compounded drugs as a result of these split court decisions?

Ms. Hamburg. It has created a very challenging situation where we have, you know, contrasting legal regulatory frameworks for our actions. 503(a) applies in some places, and it does not--the other tool that we have is our compounding guidance that was written in 2002, but that doesn't have the force of law. It just lays out our best thinking about how to----

Ms. Castor. So then the States have primary responsibility over compounding----

Ms. Hamburg. It is very clear that States have the day-to-day, routine responsibility for overseeing compounding facilities.

Ms. Castor. And then you have an industry that has evolved, that now some of the compounders, when you think of the pharmacy on the corner, where it is very important that a lot

of our neighbors get their customized compounded drug, but some of them now are very sophisticated enterprises that are shipping all over the place, and they are not--they don't--they have outgrown the 1997 law.

So now we have to decide how we are going to update it to address the sophistication of compounders out there, and then go after these bad actors. Because I think the majority of these compounders are on the up and up, living up to high standards. But the compounding--this is the map from the compounding industry and association, and I am afraid that that has led to some of the bad actors being able to take advantage of this situation and the gaps in regulatory authority.

Is that a good summary? Is that an accurate summary?

Ms. Hamburg. That is an excellent summary. And I appreciate your trying to help me explain this, because it is just an extraordinarily complex situation where, you know, the effort to----

Ms. Castor. Except I don't think that it is overly complex. I think there is a difference in outlook here on whether you have certain authority. And I think it is clear under the 1997 law and these court cases that compounders were exempted and are not manufacturers.

So we, the Congress, has the responsibility now to act and clarify it. And there has to be additional oversight of the States. If the States--if they are going to drop the ball and they are not--they are going--they are not going to provide proper oversight, then it is time for the Feds to step in and give FDA the tools it needs to prevent these tragedies from ever happening again.

Thank you. I yield back.

Ms. Hamburg. I don't know if I am allowed to make a comment, but I think, you know, that speaking to the complexity of the issue and the changing, evolving industry overlaid on top of a fragmented and ambiguous legal framework, it is important to understand that this notion of sort of black and white, compounder or manufacturer, you know, it just is trying to fit a square peg into a round hole.

And, in fact, you know, if the law is examined, it isn't really adequately defined, but there is this area of outsourcing pharmacies that is increasingly important in medical practice. And if we were to define all of those pharmacies that hospitals now use--they used to make--Dr. Burgess, you would appreciate this. You know, it used to be that a hospital would add the potassium chloride to the IV bag in their local--in their basement pharmacy or on the floor and give it to the patient. Now, both because of volume and, you know, concerns about making sure it is made under the best possible practices, that is outsourced to a pharmacy. They are making a product in larger volume and often not making it with a patient prescription in hand, yet it is, you know, clearly serving an important medical need.

And if we were to treat them as drug manufacturers, that would be simply impossible. They would have to submit an application, a formal application, to FDA for review and action. They would have to pay fees associated with that, as well. They would have to be subject to good manufacturing practice.

And so I think we want to work together to make sure that we have a law that clearly defines critical issues and authorities, that enables important patient needs to be addressed, but clarifies the different roles and responsibilities, and puts in place some critical authorities that are currently missing.

Mr. Burgess. I am going to interrupt you there in the interest of time. Dr. Gingrey has been waiting patiently.

And, Dr. Gingrey, you are recognized, 5 minutes for questions, sir.

Mr. Gingrey. Mr. Chairman, thank you very much.

And, of course, an extremely interesting and important hearing. Tragic in so many ways, of the lives lost and the number of cases of meningitis as a result of this bad actor.

Dr. Hamburg, Dr. Smith, pediatricians both, we appreciate your being here.

And some of the questioning, the line of questioning from both sides of the dais, both Republicans and Democrats, have being pretty tough, but they have to be. Because if we are going to change the law, if we are going to rewrite the Federal Food, Drug, and Cosmetic Act, particularly in regard to section 503(a) and the vagueness of that section and the conflicting court decisions, then we have to get this right. And I have some great concerns that we might not get it right, in regard to overreacting in regulating compounding pharmacies.

Every Member of the House of Representatives have drugstores. And they are not chain drugstores; a lot of them are just corner druggists that do compounding, where a certain product is needed by a patient, but maybe the manufactured product, it is in a base or something that they are allergic to, so therefore the local pharmacist has to reconstitute that drug--not manufacture a drug; the drug is manufactured--and just put it in a different way of giving it to the patient. It might even be in a pellet form. Think hormone replacement therapy, in some cases, or a cream or a vanishing cream or something that the patient is not allergic to.

So if we get to the point in the line of questioning that Dr. Hamburg received from our longstanding member emeritus, Mr. Dingell, about compounding pharmacies, that worries me a little bit, that we might overreact and get to the point that we are not getting at the problem.

It seems to me that this particular company, this New England Compounding Company, was an unusually bad actor, unusually egregious. And I would be very surprised if there are not multiple lawsuits and, in the final analysis, some folks serving some jail time.

And, you know, again, I can't understand why--Dr. Smith, I will direct this to you. I realize you have only been in this position for a few months. And by all appearances and from what I read, you are doing a commendable job. But, gosh, this company is going back to 1998, and a bright light has been shining on it at least since 2002. And there has to be some connection between members of this Massachusetts Pharmacy Board, I guess appointed by the Governor, I don't know for what period of time. And I think we have some evidence that there was some cross-pollination, where maybe even one of these individuals served on the board of the New England Compounding

Center or one of these sister companies. And, you know, it is just unbelievable.

The general public is so disgusted with Washington. I mean, you look, we are reading about what is going on now at the highest level of our military. And this situation where, in the 21st century, we have a Food and Drug Administration and we have State pharmacy boards, that something like this could happen. It is, like--it is almost beyond belief.

But it makes me think back to what President Reagan said in reference to the Russians and their nuclear stockpile: ``Trust, but verify.'' And that is the responsibility of this committee, this Oversight and Investigations Subcommittee of Energy and Commerce. Trust, but verify. And we are not very trusting today, as you can tell from our line of questioning. And we shouldn't be.

That judge, his widow in the previous panel talked about his contribution to society in the great State of Tennessee. And his life was lost, but he was just one of how many? Well, we are talking about far too many people.

So I would just in my last second ask you, Dr. Hamburg--and maybe Dr. Smith could comment, as well--do you think that the FDA needs, because of this, to all of a sudden have us change the law so that you and the FDA, or whoever succeeds you, has this broad authority over these little compounding pharmacies all across the country who are doing the right thing? They are not manufacturing drugs; they are just trying to provide a service, indeed, based on a prescription that has to be written.

This company was an absolute crooked operation, and they killed people. But I don't think anybody here should get confused between them and the typical compounding pharmacist at our corner drugstores all across our districts.

Ms. Hamburg. Yes. Well, I think we need a tiered approach, and that is what we are proposing in terms of the need for new legislation. I think that, clearly, the traditional compounder working locally is most appropriately overseen by the State. But this isn't, sadly, an isolated incident. This is the worst and most tragic, and it should be the last wake-up call to us. But over a period now of, you know, almost two decades, there have been problems with compounding facilities, compounding pharmacies.

And I think it reflects this gap in regulatory oversight and the fact that we really need a strong, clear, and appropriate legislation. We cannot have a crazy quilt where different parts of the country are subject to different legal frameworks for oversight. We need a tiered system that recognizes the role of traditional compounding and the role of the States; nontraditional compounding, which represents higher risks, and there should be Federal standards.

And we need to look at a set of statutorily based criteria, factors that in some combination would put people into this category: the type of product or activity, whether it is sterile processing, for example, the amount of product being made, whether it is in interstate commerce, whether it is going directly to the end-user or through a third party, and the nature of the anticipatory compounding.

And then there are some things that just simply shouldn't

be compounded, that should be manufactured by drug manufacturers subject to the full force of FDA authorities. And that would include, you know, certain things that you are well familiar with: extended release, transdermal, biologics, and other kinds of products that, because of the nature of the manufacturing, they really should be made in accordance with good manufacturing practice. They should be subject to the FDA preapproval review for safety, efficacy, and quality manufacturing----

Mr. Gingrey. Dr. Hamburg, thank you. I have gone way beyond my time, and I really appreciate the chairman's indulgence. And I yield back.

Mr. Stearns [presiding]. Sure.

The gentleman from Texas, Mr. Green, is recognized.

Mr. Green. Thank you, Mr. Chairman.

I think the questions and the testimony here today showed from all three panels the problem we have. The NECC tragedy laid bare a regulatory gap that we have between the practice of traditional pharmacy compounding and full-scale drug manufacturing.

There is no debate that we want the Federal Government to license individual pharmacists. That is a State responsibility. Nor is there a debate about whether FDA should oversee large-scale manufacturing of drugs, which is I think on a bipartisan basis what we have heard.

There have been overwhelming numbers of signals, though, about NECC, which is not your average neighborhood pharmacy.

Commissioner Smith, how many different States did NECC sell their products to?

Ms. Smith. I am not sure about all of their products, but in terms of----

Mr. Green. But they did sell it into a lot of States. Did they did sell it into Massachusetts?

Ms. Smith. Yes, they did. Twenty-three, I believe, is where they----

Mr. Green. Twenty-three States? But did they sell their products in the Massachusetts market?

Ms. Smith. Yes.

Mr. Green. OK. How many States did it send the contaminated injections that led to the outbreak?

Ms. Smith. That was the 23.

Mr. Green. OK.

Ms. Smith. They may sell into more, but that was the 23.

Mr. Green. NECC was not new to this nationwide shipping. Hadn't they been operating throughout the company--the country for about a decade?

Ms. Smith. That is correct.

Mr. Green. The Massachusetts Board of Pharmacy had been getting complaints and troubling sings from States around the country for that whole period of time. The board received complaints from Idaho and New York that NECC was inappropriately soliciting business. The board received a report from South Dakota pharmacists that NECC was sending blank forms for dosage size that you never use on one person. The board received adverse event reports from NECC products from Florida and New York. And the board received complaints from pharmacists in Texas and Iowa on how NECC was soliciting

and filling prescriptions. The board also received reports of cease-and-desist orders for NECC for in Colorado.

Dr. Smith, red flags came from across the country, and I can go over that list of States again. Wasn't it obvious that NECC was operating on such a large scale that it presented a nationwide problem of a sort that warranted greater involvement by the Federal Government?

Ms. Smith. Yes.

Mr. Green. Did the board in Massachusetts request any assistance from the FDA?

Ms. Smith. I am not aware of any specific requests. However, there were--certainly, during this most recent outbreak, we have worked together, and----

Mr. Green. OK. But they have been doing this for 10 years. And you all have records of it. Did you share those records with the FDA, those complaints?

Ms. Smith. I am not aware--I do not recall. I would have to look back to check, so I don't know the----

Mr. Green. Well, and I think that is our problem. And I have been on the committee since '97. We never included Federal regulation or compounding pharmacists because, frankly, I don't--that is licensing, and that is the State. But when they are in the manufacturing situation, which they are, then that means they should have been covered by Federal law.

And I know it is complicated and it is hard for a doctor to explain legal; it is hard for lawyers to explain some of the legal theories that the courts do. But that is the decision I think Congress needs to make. And I think we have a bipartisan agreement, this subcommittee doesn't do legislation. But, believe me, the Health Subcommittee can.

And I don't know if we can do it by the end of the term. And I know our chairman is not here, and even our ranking member. But I would hope that we could look at a very quick piece of legislation that we could have a hearing on and to correct this problem.

Because if you are a compounding manufacturer in Texas and selling in interstate commerce, it ought to be Federal law covering it. I don't expect our local pharmacy board in Texas--they go around and inspect my pharmacists, whether they be in the large pharmacies like Walgreens, in our case, or CVS, I know a Rite Aid here, or our neighborhood pharmacists. But they don't inspect, necessarily, the compounding manufacturers. And that is where Federal law needs to come.

And I will be glad to yield to my colleague, and I would hope that we would see movement on the bill on a bipartisan basis. Thank you.

Mr. Markey. Thank you.

Let me ask you this, Dr. Hamburg, when you try to inspect compounded drugs, do you get sued by the compounding industry?

Ms. Hamburg. We have been sued on numerous occasions, and we have been challenged in terms of our authority.

Mr. Markey. When you try to regulate compounded drugs as new drugs, do you get sued by the compounding industry?

Ms. Hamburg. We do not. The authority there is very clear, the expectations on drug manufacturers in terms of what they need to do to comply with FDA law.

Mr. Markey. When you request documents from compounding

firms, do they sue to block you from getting----

Ms. Hamburg. You know, we often have to go to the courts and get warrants in order to get the materials that we need. We do not have the full authority that we need to review documents.

Mr. Markey. When you are asking a drug company, Merck, when you request documents from them, do they go to court?

Ms. Hamburg. No, we have much clearer authority over drug manufacturers.

Mr. Markey. When you are inspecting Merck, do they question your authority to inspect?

Ms. Hamburg. No, they do not.

Mr. Markey. And that is why she needs authority. That is why the FDA needs authority. Because it is clear that the drug companies accept the law and the FDA's authority.

Mr. Green. As much as I agree with my colleague from Massachusetts, I yield back my time, but I would hope our committee hearing has done what we need to do and can encourage----

Mr. Stearns. Will the gentleman--I think his comments were very appropriate and bipartisan, and I appreciate that.

Do you think in your heart of hearts that the Energy and Commerce Health Subcommittee should provide more regulation and authority to the FDA before the end of the year?

Mr. Green. I think we ought to respond to the tragedy that happened, and I think we owe it to the families, but also to probably thousands of people who may not have been subject to a death in their family but an illness because of the practices of this particular compounding company. It happens to be in Massachusetts, but it could have been in any other State. But Massachusetts did have warning. There were complaints for 10 years about it.

And I would hope that we would have better interstate sharing between the States and the Federal regulatory agencies, even though they may not have had the authority, but somehow, in 10 years, they could have come to us and maybe we could have given it earlier.

Mr. Stearns. I thank the gentleman.

The gentleman from Virginia, Mr. Griffith, is recognized for 5 minutes.

Mr. Griffith. Thank you, Mr. Chairman, I appreciate it, and obviously, this is very frustrating. You know, I would like to know what kind of due diligence the FDA has the authority to do? Do you send out letters to doctors saying, where are you getting your compound medicines from, or where are you getting your supplies from? And the reason I ask that, and the same thing for hospitals, or clinics, or other medical providers, because this was not what we think of as compounding. This was manufacturing. In my small area, which is, you know, it overlaps the Roanoke Valley, the New River Valley, we have compiled a list of approximately 1,415 patients who were advised based on press reports, they were notified they could have been exposed to fungal meningitis through the tainted steroid injections and other products made by the New England Compounding Center, and we have, you know, a hospital that didn't, fortunately, use it, but had it sitting on the shelf. We had--that was at the Carilion Giles Community Hospital. We

had the Insight Imagining in Roanoke and the New River Valley. We had other clinics, including Vista Eye Center, LewisGale Medical Center in Salem, and Carilion Roanoke Memorial, all of which had these products.

And when you have that many, you know, I don't represent New York City. This is a fairly, compared to other parts of the country, a fairly small area, and we have got 1,415 people who have to worry about whether or not they are going to get the disease. We have more than that who have already contracted it, roughly 50 confirmed cases in the area. Three of those, so that I am being fair, were across the line in West Virginia, but not that far from our medical centers. And when you have got that many folks affected, we are not dealing with a compounder, which is why it has been frustrating all day, I think, for members of this committee, when you keep going, our jurisdiction is not clear. Your jurisdiction was clear; these folks were manufacturing.

Now what due diligence did you take to find this out? Because these are all pretty big operations, and if you just sent them a letter saying, hey, who is providing you with various products? You know, I think they would have complied, and you would have had then the, you know, you didn't--FDA, not you--but did some work back under the Bush administration, but then it appears that the ball was dropped and that there was no--it appears there was no due diligence going on that you all weren't saying, hey, who is providing you with this stuff? Because you know what, we have got Colorado involved; we have not Tennessee involved, who made complaints in advance. And we have got 1,415 people who either live in my district, or Bob Goodlatte's predominantly, and you know, somebody wasn't paying attention.

These were not our compounding. This was not your small compounding pharmacy. These were, in fact, manufacturers. And I recognize they were violating the laws, but it is very frustrating when you come in here and say, our authority wasn't clear. These folks were manufacturing. And what are you doing now to find out if there is somebody else out there who is manufacturing under the claim that they are not, I mean, you know, spending----

Ms. Hamburg. Well, I think your question speaks directly to why we do need legislation and new authorities. Compounding pharmacies are not required----

Mr. Griffith. All right, hang on, I am not worried about compounding. I am telling you that from the evidence I have heard today, it appears that these were manufacturers. So what do you all do to find out if somebody is manufacturing illegally, because that is what I think we have here? And you keep going back to compounding, and that is why everybody is getting frustrated with you; 1,415 cases, you know, a number of States away is not a compounder. That is a manufacturer.

Ms. Hamburg. Well, I think we really do need to clarify that in legislation in terms of----

Mr. Griffith. All right. I already heard that. Let me go on to another question because I have limited time like everybody else does.

There was marketing going on, and I am going to switch to you, Dr. Smith. There was marketing going on. They apparently

were aggressively marketing bulk pricing, discounts to the clinics. You are aware of that at this point?

Ms. Smith. Well, yes, those were some of the claims, or the issues that had come up before.

Mr. Griffith. OK, and I guess if they are aggressively marketing to multiple States, did it--are there any memos, I know you weren't there, and I appreciate you coming forward and saying, look, mistakes were made. Did anybody think, hey, wait a minute, this is not traditional compounding, this is a manufacturer, we need to turn this over to the FDA and let them deal with them as manufacturers? Because that is what the evidence--notwithstanding the FDA not wanting to accept some responsibility today at all, that appears to be what happened here, is that somebody was violating the law, and pulling a fraud and claiming they were compounders when they were in fact manufacturers. Did that ever come up in any of the notes or the memos that you have seen thus far?

Ms. Smith. It hasn't come up, or we haven't found that level of conversation. What has been clear and remains clear, is that Massachusetts law requires one prescription per patient. And so the issue that has come up as you describe it, is that clearly you can't do that and still do one prescription per patient.

Mr. Griffith. Right.

Ms. Smith. One of the things we have done since this all has come to light is to, A, remind all pharmacies in Massachusetts of that; remind hospitals that if you are getting product, that it needs to be one prescription per patient, for exactly the reasons that we have been discussing.

Mr. Griffith. Well, I appreciate that.

And Mr. Chairman I know my time is up, and I appreciate this hearing being held. Earlier today you said, or somebody said there would be more hearings. I certainly hope there are, and I hope that we can get some answers on why and what we need to do, not on the compounding side but to make sure the FDA has authority, because apparently, they don't, to just check and see if we have people out there who are committing fraud on the public by claiming to be a compounder when they are in fact manufacturers.

Mr. Stearns. I thank the gentleman.

And I say to all the members we are going to go for a second round. I talked to the ranking member, she has agreed. It is not necessarily going to be the full 5 minutes, but if you--if the panel will be patient with us, there are no votes today, so we do have this unique opportunity to have a second round.

I want to continue with a little bit what Mr. Griffith indicated. He sort of indicated going forward today, have you come up with procedures and interpretations so that the manufacturers out there that are doing the same thing as NECC, that you can stop them? And I didn't--you didn't seem to give a clear answer. So what assurance do we have in the public mind and legislators that the FDA is going to prevent this from happening today because we might not get legislation? This is a lame duck session, but the Republicans control the House; the Democrats the Senate. I mean, it is going to be very difficult to get legislation through normally, even though this is a very

serious problem, and I think we are all bipartisan on this. Sometimes between the cup and the lip, it takes a while. So I think what Mr. Griffith was touching on is, what assurance can you give the public that the other NECCs that are out there, that you are going to stop them?

Ms. Hamburg. Well, I do want to underscore that I believe that we need legislation----

Mr. Stearns. So you cannot stop them unless you have more legislation?

Ms. Hamburg [continuing]. To sanction and clarify authority. In the interim, we are working very hard, working with our colleagues at the State. I mentioned that we are actively engaging with the States in order to both provide our best possible information about best practices, et cetera.

Mr. Stearns. Do you feel confident you could stop another NECC; with the jurisdiction and the understanding you have now, could you stop another NECC who is manufacturing drugs? Could you stop them today?

Ms. Hamburg. NECC was not the first, and it will not be the last----

Mr. Stearns. OK. All right.

Ms. Hamburg [continuing]. Until we work together to clarify and strengthen the laws that surround----

Mr. Stearns. Dr. Smith, you indicated in your opening statement that because of what happened, people have been fired and suspended. Is that true?

Ms. Smith. Correct.

Mr. Stearns. And you have also implemented new regulations and new oversight interpretation so that you can prevent this from happening again, is that correct?

Ms. Smith. Yes.

Mr. Stearns. OK. Dr. Hamburg, have you fired or suspended anybody at the FDA because of this tragedy? Yes or no?

Ms. Hamburg. No.

Mr. Stearns. OK, have you gone through, introspectively, looked at the agency and said, these are the regulations, these are the things we need to do to prevent another NECC? Have you done that?

Ms. Hamburg. We have done that. We have been working very hard to identify what are the authorities that we need to be able to protect the American people and to help to ensure that they get the quality drugs that they deserve.

Mr. Stearns. With the NECC incident, is it your position today that this could have been prevented by the Massachusetts Department of Public Health? Yes or no?

Ms. Hamburg. I believe that we need a stronger regulation framework----

Mr. Stearns. No, could they have, in your opinion----

Ms. Hamburg [continuing]. But I believe that different actions might have been taken with NECC that could have----

Mr. Stearns. See, the problem is that you are saying----

Ms. Hamburg [continuing]. Prevented it, and I wish that that were so, but I think we just have to look at the record, that there has been----

Mr. Stearns. Did somebody tell you to filibuster us? Is that why you are handling the questions----

Ms. Hamburg. I apologize but, you know----

Mr. Stearns. No, the question is----
Ms. Hamburg [continuing]. This is an important issue, and I care about it.
Mr. Stearns. You are saying you did not have the authority to stop this, is what you keep saying today; you don't have the authority to do it. Do you think that Dr. Smith's agency should have stopped it? Just yes or no. If you don't know, just say you don't know.
Ms. Hamburg. Well, I think that clearly, Massachusetts was working very hard.
Mr. Stearns. So you think they could have stopped it, and you didn't have to stop it.
Ms. Hamburg. They were unsuccessful, and it is, you know, was tragic. We worked hard with them to limit the----
Mr. Stearns. OK. OK. I understand.
Ms. Hamburg [continuing]. Outbreak, and we want to work with you.
Mr. Stearns. I have two more questions for you here. Is it your position today that the NECC was not a manufacturing pharmacy and that you had no jurisdiction over its business activities? Is that your position today?
Ms. Hamburg. NECC is----
Mr. Stearns. Yes or no.
Ms. Hamburg [continuing]. Registered as a compounding pharmacy.
Mr. Stearns. No, I am talking about NECC. Did they, in your opinion, in your opinion, this is the crux of the hearing now, it is your position today that the NECC was not a manufacturing pharmacy, and you had no jurisdiction over its business activity? Is that your position today? Yes or no?
Ms. Hamburg. No, that is a subject of an ongoing investigation.
Mr. Stearns. No, but you have been telling us all day today----
Ms. Hamburg. I cannot characterize.
Mr. Stearns [continuing]. That you had no jurisdiction, it is murky?
Ms. Hamburg. I cannot characterize that while there is a criminal investigation that is underway.
Mr. Stearns. Let me get more pointed. Is it your position today that the FDA could not have prevented this tragedy because you did not have jurisdiction, is that what you are telling me today?
Ms. Hamburg. I, you know----
Mr. Stearns. Yes or no?
Ms. Hamburg. I am sorry, we can speculate----
Mr. Stearns. You are in charge of the FDA. You are the chief honcho. You are the great poobah of the FDA, and I am asking you, basically, could you have prevented this tragedy, and you are saying you can't because you didn't have jurisdiction.
Ms. Hamburg. It is very hard to know if any one action that we might have taken could have stopped this terrible tragedy. I wish that I could identify what that would be. What I can't----
Mr. Stearns. FDA did nothing wrong, in your opinion?
Ms. Hamburg. No, what I am--I am not saying that.
Mr. Stearns. In 2002, when they inspected and found all of

the problems, and 2006, when they wrote the letter and said, we are going to shut you down; I mean, all of that is just too murky for you, and you don't think the FDA has any responsibility?

Ms. Hamburg. No, this is--this is not a forum, unfortunately, that enables us to speak to the----

Mr. Stearns. Well, you can speak it pretty well. We have given you lots of time.

Ms. Hamburg. I think that, you know, what we really want to do together is make sure that this kind of event----

Mr. Stearns. Oh, that is axiomatic. We all understand that, but the question is, we are trying to say that--we are trying to understand how this could be prevented, and you are saying you don't know how it could have been prevented by the FDA.

Ms. Hamburg. I think that----

Mr. Stearns. You are not even--you haven't fired anybody. You haven't suspended anybody. It is not even clear that you have actually initiated anything, so I think we are leaving with the impression that thank goodness that Dr. Smith stepped up to the plate and did something, and we are just a little unsure what you are going to do. In fact, according to the staff, we are waiting, as Mr. Dingell said, we are waiting for all of this information from your agency, and we didn't even get assurance when you were asked by the chairman and by Mr. Dingell that we are going to get all this information. I am telling you, there is so much out there that your agency has not given us, in all deference to you, Madam. I mean, you have only been there a short time, I appreciate that. We need your assurance that you will provide it.

Ms. Hamburg. We will provide the information that you have requested.

Mr. Stearns. OK, my time is expired.

Mr. Stearns. Go ahead, Ms. DeGette.

Ms. DeGette. I am pulling myself together. I am going to ask some questions.

Dr. Hamburg, I think you can agree with me that, between 2002 and 2006, the FDA made some attempts to investigate this, and they were pretty inconclusive, correct, yes or no? Yes or no?

Ms. Hamburg. I apologize----

Ms. DeGette. OK, you are not going to answer that. Let's just keep going on. OK, now, in April of 2002, the FDA began an inspection of the New England Compounding Center, correct? Yes or no?

Ms. Hamburg. Yes.

Ms. DeGette. And that inspection continued throughout the fall and winter of 2002 and 2003, correct?

Ms. Hamburg. Correct.

Ms. DeGette. Now, eventually, now, you weren't there. This was not your--it was not your job to defend what they did. But in 2002, the FDA investigators concluded, after a lot of investigation, that they--that there were jurisdictional issues, is that correct, yes or no?

Ms. Hamburg. That is correct.

Ms. DeGette. They then turned this investigation--there still was some FDA involvement, but for the most part, they turned this investigation over to Massachusetts, yes or no?

Ms. Hamburg. Yes.

Ms. DeGette. And so what happened at that point was then the FDA did have some involvement, but it was primarily Massachusetts, is that right? Yes or no?

Ms. Hamburg. That is correct.

Ms. DeGette. Now, in the meantime, you know, I will say we are just trying to get answers here because we do need to figure out how to prevent this. And if we can't prevent this kind of a thing, then shame on us, because this is a company that had black specks floating in the vials. It had cleanliness that wouldn't even be accepted anywhere in the world. And we are all sitting here wringing our hands. So we have to figure out how to give you the jurisdiction to do what you need to do, and we have to figure out how to give Dr. Smith and all of the other State regulators, like Colorado, the ability to work with you to do that. OK?

Ms. Hamburg. Agreed.

Ms. DeGette. And these inconclusive answers are not helping us. Now, the act, Section 503 of the act has all of these requirements regarding the compounders, correct?

Ms. Hamburg. Correct.

Ms. DeGette. And what it says is, a compounded drug is exempt from a variety of requirements of the Federal Food, Drug and Cosmetic Act relating to drugs to get FDA pre-approval if the drug is compounded for an individual patient based on the unsolicited receipt of a valid prescription, correct?

Ms. Hamburg. Correct.

Ms. DeGette. And it says, the drug is compounded by a licensed compounding pharmacy, correct?

Ms. Hamburg. Correct.

Ms. DeGette. So what has happened over all of these years is these drug compounders have started these great big manufacturing facilities, and then they have the illusion that they are keeping these scripts for the individual patients, but they are really not doing that. Is that correct?

Ms. Hamburg. That is correct.

Ms. DeGette. And that is part of the problem, right?

Ms. Hamburg. That is.

Ms. DeGette. OK, now, just hold off. So the other thing that has happened then, Section 503(a) says, and this goes to what Mr. Griffith was saying, is Section 503(a) says that the FDA can take jurisdiction if these compounding pharmacies are exporting more than 5 percent of their drugs to other States, correct? It says that, right?

Ms. Hamburg. 503(a), yes.

Ms. DeGette. So what Mr. Griffith is saying then, is why doesn't the FDA just enforce that? But here is the problem, Mr. Griffith, and this is what Commissioner Hamburg is trying to say. Is the Ninth Circuit has thrown out all of Section 503, and it says, it doesn't even apply. And the Fifth Circuit has said Section 503(a) only applies to advertising, and that is what that map is about.

And so what Dr. Hamburg is trying to say is, you know, we can point fingers and we can be upset, and everything, and we should be, about what happened 10 years ago, and why this operation wasn't shut down, but what we really need to think about is what are we going to do going forward to make sure

that the jurisdiction is clarified?

And I would bet you if we could all sit down and talk about it, we could agree on the same principles. We don't want the FDA having jurisdiction over the doctor and the little mom-and-pop pharmacy who is trying to make the ointment for the kid. But if it really is a big manufacturing operation, even though it is a compounding pharmacy, we need to, if the law isn't clarified now, if there is litigation, if there is a separation of court decisions in the cases, we need to fix that. And that is our job as Congress.

So I guess I would say, Dr. Hamburg, you know, I understand what you are saying, but within the--within the purview of the law as it is written now, the FDA needs to do everything it can to make sure it prevents this kind of activity. And furthermore, we have a job, we have a job to all of these victims as Congress to not try to move the lounge chairs around on the Titanic.

We have a job to clarify the law if there is not clarity in the law, and we can easily do it. So thank you, Mr. Chairman, and I yield back.

Mr. Stearns. I think we have a little time here. We could--you and I could have a colloquy here, and Mr. Griffith, you can participate in this colloquy. You are an attorney, Ms. DeGette, and I appreciate what you are saying, but I think the interpretation of what you did on the Supreme Court is not wholly explained, as you said. I am asking staff, did the Supreme Court throw out the entire was it 503(a). I don't think they threw it out. They threw out only that portion that dealt with marketing. And so for you to say they threw out the whole thing so that the commissioner and the FDA had no interpretation----

Ms. DeGette. No, no that is not what I said, Mr. Chairman.

Mr. Stearns. Well, that is what you sort of implied, and the legal problem is that the Supreme Court only did a very small portion of that and left intact the idea that the company that is manufacturing still can be determined if they are a small pharmaceutical or they are a manufacturer, so I would submit----

Ms. DeGette. Mr. Chairman, if you would like to have a colloquy, I will tell you what I said.

Mr. Stearns. I think you appreciate what I said.

Ms. DeGette. What I said was that the Fifth Circuit threw out the 503(a) provision only on advertising, and left the rest of it intact.

Mr. Stearns. Right.

Ms. DeGette. The Ninth Circuit threw out all of 503, and then the Supreme Court took cert on the Fifth Circuit--Ninth Circuit case, but they only talked about the advertising. So now it is really a big mess.

Mr. Stearns. And I agree, because of the Fifth, and Ninth Circuit, and the Supreme Court. But I don't think, and this is what you are implying, that it creates such a position that the FDA had their hands tied, and they couldn't determine what is a manufacturing and what is a small pharmaceutical. I think you still have----

Ms. DeGette. Again, you are misinterpreting what I said.

Mr. Stearns. OK.

Ms. DeGette. What I said is that there is a lack of clarity in the law and what that means is that evil-doers like this compounding pharmacy, don't feel like they have to listen to the FDA. They don't feel like they have to produce the documents when they are requested, and they sue whenever there is anything that happens. And that is the problem, is it ties the FDA's hands when they are trying to take enforcement actions against these folks even if they want to.

Mr. Stearns. OK, you are welcome to step in here, but I think I would----

Mr. Waxman. Point of order, Mr. Chairman. Whose time is it now?

Mr. Stearns. Right now, it is hers. I gave her the time, and she yielded back, and I asked her if I could have a colloquy with her, which she agreed to, and you are welcome to join in. I think this is a legal interpretation, which I think you are welcome to join in.

Mr. Waxman. Mr. Chairman, I wouldn't want to interrupt your discussion, but we do have members on both sides of the aisle waiting for their opportunity to get to the round of questions.

Mr. Stearns. Oh, sure, well, you weren't here at the time, and I would be glad to recognize you.

Mr. Waxman. It goes to your side next.

Mr. Stearns. Oh, that is right. You are right. I am going to take 15 seconds and just say the purview of the chairman is I think what Ms. DeGette is talking about between the Fifth and the Ninth Circuit Court, and the Supreme Court----

Ms. DeGette. Don't interpret what I am saying.

Mr. Stearns. I know, but I am the chairman, and what I think is that there was still left the integrity of the law so that the FDA could determine who is manufacturing and who they have jurisdiction over.

Mr. Waxman. Regular order, Mr. Chairman.

Mr. Stearns. With that, I will recognize the gentlelady from Tennessee.

Mrs. Blackburn. Thank you, Mr. Chairman, and I have just a couple of questions.

You all have stayed with us, and I do appreciate this.

A point of clarification, Dr. Hamburg. You mentioned earlier there are 7,500 advanced compounding pharmacists and 3,000 sterile.

Ms. Hamburg. That is information that was given to us by the International Association of Compounding Pharmacies.

Mrs. Blackburn. OK, well, that is what I want to know if that was----

Ms. Hamburg. We don't know the numbers because they are not required to actually report to us, so we don't know numbers from our own assessments.

Mrs. Blackburn. OK, but you can source that for us? Would you provide that sourcing so that we have that?

Ms. Hamburg. OK, certainly.

Mrs. Blackburn. OK, thank you, I appreciate that. Let me, I want to go back to this issue that you all had because you had the Colorado complaint against NECC in May of 2011, is that correct?

Ms. Hamburg. That is correct.

Mrs. Blackburn. OK. And that complaint came into you well

in advance to any of these contaminated lots being shipped, is that also correct?

Ms. Hamburg. Well, as I understand it, it was a request for information from us about whether they were registered as a manufacturer, a drug manufacturer, and they--NECC is listed as a compounder.

Mrs. Blackburn. Well, I think Colorado notified the same FDA compliance officers who had inspected NECC in the past, is that correct?

Ms. Hamburg. I believe.

Mrs. Blackburn. And that these inspectors were aware of NECC's past violations, isn't that correct?

Ms. Hamburg. I believe that the email from Colorado was shared within the FDA because of the history with NECC.

Mrs. Blackburn. OK, and then, in that email, did they not say that NECC was again shipping volumes of drugs without a prescription?

Ms. Hamburg. What they indicated to us was that they were concerned that NECC was operating in violation of Colorado State Board of Pharmacy licensure and registration laws, and they included attachments----

Mrs. Blackburn. OK. Doctor.

Ms. Hamburg [continuing]. About the volume of product that was being shipped.

Mrs. Blackburn. But it was clear that it was a repeat violation, isn't that correct?

Ms. Hamburg. What was clear was there were not specific safety and quality concerns, but they were noting that there were not valid prescriptions for the materials that were being sent to Colorado.

Mrs. Blackburn. OK, let me ask you this. Did the FDA do anything at all with that complaint?

Ms. Hamburg. Well, we suggested that they follow up with the Massachusetts Board of Pharmacy because----

Mrs. Blackburn. You suggested? You suggested; you didn't require. Did you even pick up the telephone and call the Massachusetts Board of Pharmacy and say, ``We think we have a repeat offender''?

Ms. Hamburg. I understand, you know, what you are getting at there, but it----

Mrs. Blackburn. Yes or no. Did you pick up the phone and call? Did anybody pick up the phone and call?

Ms. Hamburg. Email was being used, but it was communicated through the Colorado Board of Pharmacy.

Mrs. Blackburn. Would you like to supply all of those emails to us for the record?

Ms. Hamburg. I believe you have them.

Mrs. Blackburn. OK, we have got all of those in total. When did you personally become aware of the situation? I mean, at what point in the process did you individually, not your staff, but you? When did you hear of it.

Ms. Hamburg. When the first cluster of meningitis cases and the possible link to NECC was identified. It was in late September.

Mrs. Blackburn. OK, Dr. Smith, let me come to you with my last minute. Did the FDA ever contact you?

Ms. Smith. Are you--just so I can understand, do you mean

in the past or around this current outbreak?

Mrs. Blackburn. No, let's go back to the Colorado complaint. Did they ever contact you? Did you ever--did you ever get a phone call or an email from anybody that said, we think we have a repeat offender out here?

Ms. Smith. Well, I can't speak to the phone calls, but review of the emails does not suggest that we got any information then.

Mrs. Blackburn. So they knew they had a repeat offender, but they did not call you.

With the boards of pharmacy, like with Colorado, back to you, is there any direct contact there? You know, so many of our State boards, who do a great job of regulating areas, contact and work with other State boards who have like supervision in their States.

Ms. Smith. Well, we did receive information from Colorado about the action, but it wasn't until July of 2012, and we weren't, or I wasn't aware of that until we discovered that in the process of producing the documents for this committee.

Mrs. Blackburn. OK, and let me ask you this: Personnel actions in response to this, the NECC, have you taken any actions there?

Ms. Smith. Yes, the executive director at the time has been let go from the department, and the board counsel has been put on administrative leave as was the division director for that area.

Mrs. Blackburn. And are you reviewing your processes and best practices?

Ms. Smith. Regarding personnel actions?

Mrs. Blackburn. Yes.

Ms. Smith. Yes, as we reviewed the information, again, that we presented for this committee, we have identified lapses in judgment, which have resulted in these personnel actions.

Mrs. Blackburn. Thank you. I yield back.

Mr. Stearns. The gentleman from California, Mr. Waxman, is recognized for 5 minutes.

Mr. Waxman. Thank you, Mr. Chairman.

I find this hearing amazing.

Mr. Stearns. Amazing.

Mr. Waxman. Because what we need to do is to work together to solve a problem and make sure it will never happen again. Instead what I hear from my Republican colleagues is they want to prosecute the director of the Food and Drug Administration. Did she know this? What action did she take?

It sounds like Massachusetts has a lot to be apologetic about. Isn't that a fair statement, Dr. Smith.

Ms. Smith. Yes, you are right.

Mr. Waxman. And the question is, did FDA fail to do things they should have done? Well, it sounds like you could have done more. The FDA as an institution could have done more. The first time they wrote a letter was in 2006, saying that this thing seemed to be--this company seemed to be out of control. And then they didn't do anything after that.

Now, I have a feeling, Dr. Hamburg, you are being picked on because you are part of the Obama administration, and Republicans have been picking on Obama for 4 years, and usually their mantra goes, job-destroying regulation, let industry

police itself, we don't want government involvement.

Now, they are saying, we want more government involvement, and I think they are right. We want appropriate government involvement to stop these things from happening.

So you would think that our obligation would be to figure out, do you have the authority? I respect the chairman greatly, but I have never understood him to be a great legal scholar. It seems to me there is some ambiguity. If there is an ambiguity it is our job to clear it up. You think there is an ambiguity because the law that we drafted in 1997 said one thing and the court came in and said something else. You don't know whether you can act, whether you can't act. If we want to make sure you act in the future, other than just beat you up for not acting, we ought to make sure that you have all of the authority appropriate to act. The courts have thrown out part of that 1997 law. The courts are themselves divided on whether Section 503(a) continues to have any legal force. In the Western States, 503(a) is not effective; while in Texas, Louisiana, and Mississippi, it is. And as the map is put together by the compounding industry itself shows, there is a very large gray area in-between.

So why are we looking for anybody to blame other than the company and making sure that the regulators have all of the power that they need. That involves, my colleagues, regulatory power to act. It also involves, I tell you regulators, to do your action, to take action to stop these bad actors from doing what they want.

And I wasn't in the room, but I understand the chairman of the Oversight Committee said, they are not going to do any legislation. Well, I would rather we do it now before he leaves. Because he is so involved and steeped in this whole question, he should want to work with us to solve this problem. It doesn't sound like that difficult a problem. We need to say the FDA has the authority to do this, to do this, to do that.

Commissioner Hamburg, can I ask you for a commitment to make your staff available to us this week if we started a process to----

Ms. Hamburg. Absolutely, tomorrow. We are so eager to work with you because we feel there are significant gaps in our authorities that limit and undermine our ability to do all that we want to do to protect the health and safety of the American people. You know, I think that the fact that we have a situation like that map reveals, suggests that we don't have a comprehensive, integrated legal framework for action, and we think that we can work with you to identify critical areas from registration, so we know who is out there, and what they are doing, to developing Federal standards that should be adhered to to ensure safe and high-quality products, to the ability to do full inspections.

Mr. Waxman. I don't want to get you off the hook completely. I think you need the law to be clarified, but if I were sitting in your shoes--that is a mixed metaphor--if I were sitting in your seat and I was the head of the FDA and I heard that Colorado was concerned about this situation, and you heard other reports, I would have assumed I had jurisdiction. I would have assumed the jurisdiction. I would have acted on it.

And I have to say to the State, you know, people want to

make partisan comments, and I think what some of what is going on is a little partisan. When FDA first sent the letter, the chairman said when you sent a letter, was the FDA under the Bush administration? When the State of Massachusetts had a weak consent agreement, it was under Governor Romney's administration. You are now here under Governor Deval Patrick and here under President Obama. Let's put partisanship aside. Let's make sure you have the authority and the resources to do the job. We want you to do the job because we ought to be mindful of the comments that Mrs. Lovelace made and all of the other people who are waiting to see if they are going to die from this contaminated drug.

We don't want excuses. We don't want to leave this law ambiguous because you are sued if you act. And if you act, assuming you have authority when you don't, you are usually called before committees to say, how could you act as if you have authority when Congress didn't give it to you?

I think we ought to put our partisanship aside. The election is over. Figure out a clear law for the Federal Government to be able to act because, because with all due respect, this is not a State issue if a drug is being shipped around in the country. It is an interstate issue.

Thank you, Mr. Chairman.

Mr. Stearns. Sure, and I will be the first to recognize-- to recommend you as you as chairman of the FDA.

Ms. DeGette. Can we finish this hearing, please?

Ms. Hamburg. Might not want that job.

Mr. Stearns. All right, Dr. Burgess is recognized.

Mr. Burgess. Thank you, Mr. Chairman.

And something that is very important, I don't want it to get lost in the translation. Representative Blackburn asked about emails between the FDA regional office, and the Massachusetts Board of Pharmacy.

And Mr. Chairman, may I suggest that those emails are a critical part of our investigation and that we must receive those, even if it is necessary to exercise subpoena authority. We need access to that critical part of the----

Mr. Stearns. If the gentleman will yield for one second. We have tried. We have got no emails from the FDA. The crux of this hearing is to get to the bottom of what happened. We can't get to the bottom if we don't have the information. So you are exactly right. The FDA has got to cooperate and give us the emails, because we have gotten zero.

Mr. Burgess. Well, and of course, the FDA has a lot of material, and the access to the opinion of your experts would be important to us in this investigation. So the intransigence that Chairman Upton referenced in his opening statement is something that really must be overcome. Now, I am of the opinion that you had all of the authority that you needed, and yes, it was a previous commissioner, and it was a previous administration. So, once again, I would also ask that if there is a memo from a general counsel at FDA to the then commissioner about, you don't have the authority to do what you said you were going to do in this enforcement letter, I think the committee really should see that as well. And again, I think we should exercise every power that we have in order to get that. And the reason it is important is if new legislation

is indeed passed and passed hurriedly, as has been recommended, before the end of the year, and yet you are not going to act on that authority, then we are going to be right back here in the same soup with the same problem at some point in the future, and it may be a different commissioner from the FDA and they will say, well, there was an ambiguity. Look, there is no ambiguity. You have got a criminal investigation going on against NECC, is that not correct?

Ms. Hamburg. There is a criminal investigation, yes.

Mr. Burgess. So where is the ambiguity? If you have a criminal investigation, if you had all of the guys in FDA jackets seizing computers out of the compounder, where is the ambiguity?

Ms. Hamburg. First, let me say, we are working to get you the emails that you want. We have been trying to develop documents and get them to you as swiftly as we can in light of everything that is going on. You know, I know it is not the answer that you want to hear, but I do think that there is clearly ambiguity and a lack of----

Mr. Burgess. A criminal investigation, guys in FDA jackets seized the computers, did it on TV so everybody can see. That doesn't look ambiguous----

Ms. Hamburg. No, but--the need for legislation. You know, I want to do everything to work with you and get you the information that you need, but I think we also do need to look forward and look at where are the gaps in authority.

I cannot speak to what was going on in the FDA during that period because, as has been noted, I wasn't there.

As I understand it, there were very intense discussions and conflicts about what were our authorities, what--there was ongoing litigation; what basis would we use for different regulatory actions that might be taken.

Mr. Burgess. So help us here. If we are going to craft legislation rapidly before the end of the year, as has been suggested several times on the other side of the dais, how do we keep from making the same mistake again? Look, do you have the authority to conduct an investigation as to whether or not you have jurisdiction to conduct an investigation because that is what I have been hearing all day?

Ms. Hamburg. We have authorities that have been consistently contested, have resulted in split court decisions, in a patchwork of regulatory legal oversight, and you know, that is part of what I think we can and should address together.

Mr. Burgess. Yes. Look, people are dead. Doctors have administered medication that they thought was safe, and their patients have suffered. They have got to live with those consequences. The case we heard about today where the doctors in the intensive care unit at Vanderbilt Hospital didn't have a clue as to what was really the culprit in that gentlemen's illness. There is a lot of stuff here that, if there is a problem with the existing statute, it needs to be corrected. Then you owe us the ability to look at those internal documents and see what the discussion----

Ms. Hamburg. And we will get that to you.

Mr. Burgess. Well, it has been said time again, we have to do this before the end of the year, give us the stuff. Mr.

Chairman, I am going to ask that we subpoena the stuff that we need, and do that forthwith. I mean, yes, I know it is holiday season and nobody wants to be working on this stuff, but we have got to do it. And if we rapidly produce legislation so that we can just say we have done something before the end of the year so we can all feel good about ourselves, again, we are going to be back here in the same mess, 2 years, 3 years, 4 years fill in the blank. If all you need for the cloak of invisibility is to say you have a compounding pharmacist, I mean, what is to stop Pfizer tomorrow from saying, oh, I am a compounding pharmacist. All of this stuff goes out the door and you can't stop me. You can't touch me because the Fifth Circuit or the Ninth Circuit or someone said, you can't touch me. That is nonsense. No one believes that that is the way it should be, and surely, you don't either.

Ms. Hamburg. I do not. And that is why I really do feel this is an extraordinary opportunity for us to fix some of those problems that have really been present for now at least 15 years and have tragically resulted in incidents involving deaths, loss of vision, other injuries and harm from drugs that the patients thought would help them, not harm them. So I think we can strengthen----

Mr. Burgess. Look, you owe us the information you have.

Ms. Hamburg. And we will get that to you.

Mr. Burgess. You have emails. You have experts under your control. If this is something that has been discussed internally, and there has been a conflict internally, let us be privy of that information so that when we try to craft the legislative fix, it is not an imperfect product. And you have got all of the authority you need today to shut this place down, lock them up, and send them away for however long that anyone would care to think, for whatever reason, it didn't happen in 2002, 2004, 2006, 2008.

Mr. Stearns. The gentleman's time has expired.

Mr. Burgess. I yield back.

Mr. Stearns. Mr. Dingell, before I recognize Mr. Dingell, Dr. Hamburg, we have gotten thousands and thousands of emails from Dr. Smith's agency, so the fact that you have got none--she has less resources than you do, yet they complied and have given us all of the information. So I just really urge you and your staff to comply.

Ms. Hamburg. We will get that to you.

Mr. Stearns. All right, Mr. Dingell is recognized for 5 minutes.

Mr. Dingell. Mr. Chairman, thank you.

Dr. Smith, and commissioner, it is possible for the two of you to execute Memorandums of Understanding defining your respective jurisdiction, is it not?

Ms. Hamburg. Yes.

Mr. Dingell. Is there any reason why you could not or would not begin to devote your attention to achieving such a Memorandum of Understanding so that you could define where the authorities of Food and Drug lie, and the authorities of the agency in the State of Massachusetts lie? Are you willing to undertake that, ladies?

Ms. Smith. Well, I certainly think that there are multiple opportunities for us to do better in terms of communication and

that sort of thing as a beginning.

Mr. Dingell. We are going to try, I think you can sense from the committee and its questions to proceed towards a legislative solution, and it may very well be that we have to do so, and I think we are determined to do so.

What I am hoping is that while we are doing that, that you will commence doing what you have the capacity to doing, i.e. A Memorandum of Understanding, where the two of you define your respective responsibilities so that we can get ahead of this curve. And if we cannot complete our business by year end because of the Senate or other things, that we are able, therefore, because of your labors, to commence the process of moving along on a parallel track. Are you willing to do that?

Ms. Hamburg. We are certainly willing to do that, and we are pulling together all of the 50 States in order to really begin----

Mr. Dingell. Well, I don't want to put out difficulty for you, but I want to look at how to resolve the problem.

Ms. Hamburg. But I just have to underscore that it still won't address what the courts say, different regulatory requirements.

Mr. Dingell. Doctor, the clock runs, and it is most uncharitable.

I will look for you to give me an answer on what you can do to get a Memorandum of Understanding done between your two agencies and/or other agencies.

Now, it is possible to define a compounder as a person who makes certain amounts and to define a manufacturer as a person who makes certain amounts of pharmaceuticals, is it not? Yes or no?

Ms. Hamburg. You could decide to put that in legislation. Currently, that does not exist in the legislation.

Mr. Dingell. You are telling me you don't have the authority to do that? You do or don't have that authority?

Ms. Hamburg. Volume in and of itself is not dispositive. It could be put into legislation as a statutory factor in our determination.

Mr. Dingell. It appears that the New England Compounding Center and other like-hearted rascals have engaged in the practice of figuring themselves a fine loophole in which, through lobbying and other efforts, they have been able to assure that they are able to engage in practices that impose substantial dangers on the American people.

Now, having said that, I would like to have you tell me one more thing here, if you please, Doctor.

You have one of the required treatments for this particular fungicidal meningitis that takes place is to have availability of a substance called oral voriconazole, which is a therapy used in treating spinal meningitis. There is a great concern on the part of a hospital in my district St. Joseph Mercy in Ann Arbor, and they are troubled that there is going to be a shortage of this particular pharmaceutical available to them to provide the necessary treatments for their patients who have been hurt by this particular--the particular injectable that we are talking about today.

What is there that we can do to assure that there is an adequate, current, and future supply chain for oral

voriconazole?

Ms. Hamburg. Well, voriconazole has been used in the treatment intravenously, and from the very beginning, we have been looking at the possibility of shortages. When last I discussed that with----

Mr. Dingell. What are we going to do about that?

Ms. Hamburg [continuing]. They did not feel it was in shortage. I have not heard anything further. I will get back to you if there are concerns, but I do not believe that it is at risk for shortage at the present time.

Mr. Dingell. This is a matter of urgent concern, and I would suspect that my people at St. Joe's are concerned that you all have hospitals and practitioners elsewhere in the country who all have the same concern. So I would appreciate if you can look----

Ms. Hamburg. Yes, we will be examining that.

Mr. Dingell [continuing]. Into that.

Mr. Chairman, I thank you for your courtesy.

Mr. Stearns. The gentleman from Virginia is recognized for 5 minutes, Mr. Griffith.

Mr. Griffith. Mr. Chairman, this is probably a first for me in the time that I have served on this committee, but I agree with Mr. Waxman when he said that he would have made the assumption, particularly in those areas that are gray, that you had the authority. And so I just point that out to you.

Now, maybe it is because I was a criminal defense attorney in my prior life, you know, the threats that somebody might sue me just aren't something that would stop me from trying to do my job. And if I thought I was right, I would have gone forward. And that is why we want to see the emails, and we want to see the memorandums. You have heard all of these questions, and I thought Ms. DeGette did a nice summation. And I wish you would have been as clear in your answers as she was in trying to interpret your position.

But having been a criminal defense attorney and having heard you all day say that, you know, you didn't have authority or your authority was vague, or you needed clarification of authority, I have to ask the question, what is your legal basis for the FDA going in and doing a criminal investigation in this case?

Ms. Hamburg. Well, of course, that is being done with the Department of Justice, but the Food, Drug, and Cosmetics Act, obviously, is the basis for so much of our regulatory actions, but the problem here is that a component of 503(a) has been questioned in the courts, and it applies in some areas and it doesn't apply in other areas. And we have, around compounding pharmacies, we have guidance that we have put out that would be applying in some areas, but that doesn't have the force of law. So, you know, it is a challenging arena for regulatory----

Mr. Griffith. Well, here is the problem, and I fear that in your comments today, you may have made the argument for the defense that they are going to escape criminal sanctions because you have said the law is ambiguous and that you don't have the authority to go forward. And I think that is a mistake because, look, you know, I think, as I said before, they are a manufacturer, particularly when we have 1,415 patients in my area alone. I think they are a manufacturer. And just because

they call themselves a compounder doesn't make it so. I could call myself the Duke of Earl and claim diplomatic immunity. That does not make it so. In a trier of fact, if you all had been aggressive on this, I believe a trier of fact would have found they were weren't a compounder a long time ago, which is why, as you move forward, you didn't answer the question earlier, so I am assuming that you don't routinely contact medical professionals and ask them where they are getting their drugs from so that you couldn't identify. I think that is what you should have been doing, but hindsight is 20/20, as we all know.

But I think you ought to be looking at doing something like that in the future so that you can protect the American public. I think, like Mr. Waxman said, you should have assumed you had the authority when you had a bad actor. And I think as you go forward, you have to look at that. And Dr. Smith, I would hope that you all would look--I believe they may have undermined their criminal case today. So since they said it was a State's responsibility, perhaps there is a State law that you could look into and ask your attorney generals to look and see if there is any criminal prosecution that could be brought under State law, because if FDA doesn't have the authority to deal with them from a regulatory standpoint, I am not sure they have the authority to go in and seize the computers and do what they are doing.

That being said, I would now yield my time to the gentlewoman, Congresswoman Blackburn.

Mrs. Blackburn. Thank you. I appreciate that, and Dr. Hamburg, I want to go back to this issue with the emails that pertain to NECC. The first violation came up in 2002, and please understand that it was unclear in your answer to me about the emails. You seemed to indicate you thought we had your emails. We do not. So let me be very clear: We want to see this entire file going back to 2002. We want all of those emails, and we want the conversation that took place via email with the Massachusetts Board of Pharmacy.

I have 81 Tennesseeans and 13 deaths. We are very concerned about this. We are concerned about everyone that has been adversely impacted. Our sympathies and thoughts are with them, and we are incredibly concerned about the ineffectiveness of the bureaucracy, and it doesn't matter which administration. It is the lack of attention by this agency to a situation that has gotten out of hand.

So just to be certain that you understand what we are asking, all of the emails, we are not in possession of this. We are--and we have asked for this. So we do ask that you comply quickly, so that we can see the full extent to your participation and the manner in which you all communicated with, responded both on an intra-agency, and then also with the Massachusetts Board of Pharmacy.

And with that, I will yield back the balance of my time.

Mr. Stearns. The gentlelady's time--gives up her time, and the gentleman from Massachusetts is recognized for 5 minutes.

Mr. Markey. Thank you, Mr. Chairman, very much.

Dr. Hamburg, isn't it true that the legal definition of drug manufacturer in Section 510 of the Food, Drug, and Cosmetics Act exempts pharmacies?

Ms. Hamburg. You know, I am not a lawyer, but my understanding is yes.

Mr. Markey. Yes. So that creates a problem right up front from a legal perspective.

Ms. Hamburg. Yes.

Mr. Markey. That clear statement that exempts pharmacies from FDA jurisdiction, and when it comes to drug manufacturers, that in the actual definition itself, it kind of talks about what would be equivalent of Merck, Bayer, or Pfizer as a manufacturer, and then it explicitly says pharmacies aren't covered, you know, in that definition. So that is just loaded with potential for lawsuits, you know, for questions that can be raised about your authority, and do you need that clarified so that you absolutely have the ability to regulate compounding pharmacies in a way that protects the public health and safety?

Ms. Hamburg. I think that 510 exempts from registration, not any kind of jurisdiction, but I think the problem is that--I am not saying we have no authority. I am saying that our authority over drug manufacturers is very different, and it requires a set of clear actions on the part of the manufacturers and the part of FDA.

In this area, it is simply much more murky, and it is contested in the courts, and we have a split court decision. We have different legal frameworks that govern different States, yet we have an industry that operates across State boundaries.

We don't have the kind of authorities that we need, and we don't have the kind of clarity of the legislation that we need as well, you know. I am deeply troubled by what has happened in this case and with NECC, and if there were actions that could have been taken at an earlier time to prevent it, I would wish that that were so.

But you know, what I am speaking to now is, we have this opportunity. It is a clarion call to action, I think. And if we don't want to see that kind of event repeated, and it is not an event that has occurred in isolation, you know. There have been events in so many Members' districts in the past over a period of many years, that I think we have an obligation to work together to create new legislation that defines this in a way that is clear and understood and that gives FDA new authorities.

Mr. Griffith mentioned, you know, why aren't we writing to compounders, or why aren't you writing to patients telling them that they might be getting drugs from compounders? Well, we don't even know the universe of compounders and what they are making. So we clearly need additional authorities in order to achieve some of this goals that we have been talking about.

Mr. Markey. And, Doctor, that is why I listed the individual component parts of my legislation, just so it could be clear that you would welcome that authority. And then we could ensure that you can be the true cop on the beat.

But I do believe that it is troublesome that in the legal definition of ``drug manufacturer,'' the legal definition in the FDA statute, it actually exempts pharmacies in that definition.

So the whole area is just rife with ambiguity. And in that atmosphere of ambiguity, we have wound up with a mess on our hands. And we just have to make sure that that never happens

again.

Mr. Chairman, I thank you so much.

Mr. Stearns. Thank you.

And I would say to the panel, we have completed our questions here. And, as the chairman, I have usually the ability to say the last few words. And in defense of Mr. Markey, who had made the case, in his words, as murky, I go back to what Mr. Waxman said, that if he was chairman of the FDA, he would not have been cautious; he would have been siding on safety and gone through and exercised, regardless of what the situation. I agree with him, and that is why I think he probably should consider being the commission chairman.

And, also, I would say to you, if Pfizer or Merck or any large pharmaceutical company suddenly call themselves a compounding company, you are implying that you wouldn't have jurisdiction over them, when we know that is not true. In fact, you know, when you look historically, you see lots of criminals that are being indicted; they make the case that, ``I was doing work for the FBI under cover.'' And, lo and behold, that was just a front so that they could defend themselves when, actually, they were committing fraud and criminal activity.

And, lastly, I would just conclude, Mr. Griffith and Dr. Burgess both mentioned the FDA appears to have the legal authority to walk in and take computers with their jackets, we have seen on television. And, certainly, if you had the ability to go in and prosecute and take the computers from NECC, then surely you had the jurisdiction to shut them down, because you had the jurisdiction to go in and take their equipment.

And, certainly, I think many of us in this committee are disappointed that you are not providing the emails and information we need so we can get to the bottom of this. And that was the intention of this whole hearing, is to see what really happened.

So, with that, the subcommittee is adjourned.

[Whereupon, at 2:00 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]